

Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kenny, Dermot [ (b) (6) Kublin, James (b) (6) ; Li, Rose [ (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]

**Subject:** ACTIV Clinical Trial Capacity Working Group - reporting meeting  
**Attachments:** Clinical Trial Capacity Working Group Meeting Agenda\_07142020.pdf  
**Location:** [\(b\) \(6\)](https://fnih.zoom.us/j/(b)(6))

**Start:** 7/14/2020 1:00:00 PM  
**End:** 7/14/2020 2:00:00 PM  
**Show Time As:** Tentative

**Required Attendees:** Bascles, Lionel; Cohen, Myron; Corey, Larry; Davey, Victoria; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Garner, Carlos; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Mensah, George; Nayak, Seema (NIH/NIAID) [E]; Payton, Manzine; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Takas, Therese; Vincent, Mike; Weinmann, Gail; Stratton, Ben

**Optional Attendees:** Wachtel, Jonathan; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Ardiffe, Bernadette; Criffield, Robin; Hamilton, Nancy; Melencio, Cheryl (FNIH) [T]; Minnich, Beth; Mueller-Reichenstein, Petra; Pico, Dianna; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] ( (b) (6) Zoe (NIH/NHLBI) Hill [C] ( (b) (6) Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E] ( (b) (6) Carluccio, Dana; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Kenny, Dermot; Kublin, James; Li, Rose; Menetski, Joseph (FNIH) [T]; Qashu, Felicia; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Elsaid, Olivia

Dear WG members; During this call we will share some exciting updates regarding the development of the 'playbooks'; and we will have an important discussion about updating the site survey for NCATS. Looking forward to the call and hope you can make it! Karen

Dear Clinical Trial Capacity Working group members - As the tiger teams continue to work closely with ACTIV protocol development and operations teams, and the 'playbook' development teams ramp up to quickly develop these resources, we will reduce the number of times the full WG meets in July to every other week (July 14th and 28th). Best, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting  
[\(b\) \(6\)](https://fnih.zoom.us/j/(b)(6))

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**From:** Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]  
**Sent:** 7/30/2020 11:33:41 AM  
**To:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]  
**Subject:** RE: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

OK.

---

**From:** Adam, Stacey (FNIH) [T] <(b) (6)>  
**Sent:** Wednesday, July 29, 2020 11:05 PM  
**To:** Wholley, David (FNIH) [T] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Anderson, James (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)>  
**Subject:** RE: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Hi Team,

I just confirmed with the ACTIV-3 team they will be testing a subset of the patients from ACTIV-3, but it will be done under a separate protocol called INSIGHT 004 that is open at certain sites where the trial will be activated.

Thanks,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnerships  
Direct: (b) (6) | Mobile: (b) (6)

---

**From:** Wholley, David (FNIH) [T] (b) (6)  
**Sent:** Wednesday, July 29, 2020 9:53 PM  
**To:** Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Collins, Francis (NIH/OD) [E] (b) (6) ; Freire, Maria (FNIH) [T] (b) (6) Austin, Christopher (NIH/NCATS) [E] <(b) (6)> ; Tabak, Lawrence (NIH/OD) [E] (b) (6) Anderson, James (NIH/OD) [E] (b) (6) ; Parker, Ashley (NIH/OD) [E] (b) (6)



**Cc:** Adam, Stacey (FNIH) [T] < (b) (6) >

**Subject:** RE: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Stacey said there is collection of samples for genetic characterization in ACTIV-3. Copying her for clarification.

---

**From:** Lane, Cliff (NIH/NIAID) [E] (b) (6)

**Sent:** Wednesday, July 29, 2020 6:20 PM

**To:** Wholley, David (FNIH) [T] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Freire, Maria (FNIH) [T] (b) (6); Austin, Christopher (NIH/NCATS) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Anderson, James (NIH/OD) [E] (b) (6); Parker, Ashley (NIH/OD) [E] (b) (6)

**Subject:** Re: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

(b) (5)

Cliff

---

**From:** "Wholley, David (FNIH) [T]" (b) (6)

**Date:** Wednesday, July 29, 2020 at 5:58 PM

**To:** "Collins, Francis (NIH/OD) [E]" < (b) (6) >, "Freire, Maria (FNIH) [T]" (b) (6), "Austin, Christopher (NIH/NCATS) [E]" (b) (6) >, "Lane, Cliff (NIH/NIAID) [E]" (b) (6) >, Lawrence Tabak < (b) (6) >, "Anderson, James (NIH/OD) [E]" < (b) (6) >, "Parker, Ashley (NIH/OD) [E]" < (b) (6) >

**Subject:** RE: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Francis, I composed the following reply to Robert for your consideration. I'm happy to send it (he wrote to both of us) or you can; feel free to edit of course in either case. Cliff, please weigh in on how I have characterized the NIAID study you mentioned this morning. Thanks

Hi Robert:

(b) (5)

Regards,  
David

---

**From:** Collins, Francis (NIH/OD) [E] (b) (6)

**Sent:** Wednesday, July 29, 2020 7:43 AM

**To:** Freire, Maria (FNIH) [T] (b) (6); Wholley, David (FNIH) [T] (b) (6); Austin, Christopher (NIH/NCATS) [E] (b) (6); Lane, Cliff (NIH/NIAID) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] < (b) (6) > Anderson, James (NIH/OD) [E] < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) >

**Subject:** FW: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

**From:** Plenge, Robert (b) (6)  
**Sent:** Wednesday, July 29, 2020 7:33 AM  
**To:** Wholley, David (FNIH) [T] (b) (6) Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** Re: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Given the recent genetic data ([here](#), [here](#), [here](#), [here](#)), is it worth considering more routine genetic testing (e.g., GWAS, WES) in ACTIV trials to guide future repurposing?

**From:** "Melencio, Cheryl (FNIH) [T]" (b) (6) > on behalf of "Wholley, David (FNIH) [T]" (b) (6)

**Date:** Tuesday, July 28, 2020 at 10:55 PM

**To:** "Austin, Christopher (NIH/NCATS) [E]" (b) (6) "Bancel, Stephane" (b) (6)  
"Carter, Kara" (b) (6) > "Cavaleri, Marco" (b) (6)  
"Cihlar, Tomas" (b) (6) > "Collins, Francis (NIH/OD) [E]" (b) (6)  
"Corey, Larry" < (b) (6) "Culp, Michelle (NIH/OD) [E]" (b) (6)  
< (b) (6) "Disbrow, Gary (OS/ASPR/BARDA)" (b) (6) "Dolsten, Mikael" (b) (6)  
< (b) (6) "Erbelding, Emily (NIH/NIAID) [E]" < (b) (6) "Erck, Stan" (b) (6)  
< (b) (6) "Fauci, Anthony (NIH/NIAID) [E]" (b) (6) > "Freire, Maria (FNIH) [T]" (b) (6)  
> "Gadbois, Ellen (NIH/OD) [E]" (b) (6) > "Gibbons, Gary (NIH/NHLBI) [E]" (b) (6)  
< (b) (6) "Hudson, Thomas" (b) (6) "James, Stephanie (FNIH) [T]" (b) (6)  
< (b) (6) "Johnson, Robert (OS/ASPR/BARDA)" < (b) (6) "Kramer, Lynn" (b) (6)  
( "Lane, Cliff (NIH/NIAID) [E]" (b) (6) "Lepore, John" (b) (6)  
b (b) (6) "Marks, Peter (FDA/CBER)" < (b) (6) "Marston, Hilary (NIH/NIAID) [E]" (b) (6)  
> "Mascola, John (NIH/VRC) [E]" (b) (6) "Meeker, David" (b) (6)  
> "Menetski, Joseph (FNIH) [T]" (b) (6) > "Messonnier, Nancy (CDC/DDID/NCIRD/OD)" (b) (6)  
> "Pandya, Hitesh" (b) (6)  
< (b) (6) "Pangalos, Mene" (b) (6) > "Pao, William" (b) (6)  
(b) (6) "Parker, Ashley (NIH/OD) [E]" (b) (6) "Paul, Steve" (b) (6)  
< (b) (6) "Perlmutter, Roger" < (b) (6) "Plenge, Robert" (b) (6)  
(b) (6) "Plump, Andy" < (b) (6) Rachel Ramoni (b) (6)  
(b) (6) > "Rasi, Guido" (b) (6) "Reed, John" (b) (6)  
(b) (6) "Reese, David" < (b) (6) "Rouse, Doris" < (b) (6) "Santos, Michael (FNIH) [T]" (b) (6)  
> "Skovronsky, Daniel" (b) (6) "Stein, Peter (FDA/CDER)" < (b) (6)  
> "Stoffels, Paul" (b) (6) "Tabak, Lawrence (NIH/OD) [E]" (b) (6)  
> "Talley, Michael" (b) (6) > "Tsai, John" (b) (6)  
(b) (6) "Vessey, Rupert" (b) (6) "Virgin, Skip" (b) (6)  
"Wholley, David (FNIH) [T]" (b) (6) > "Woodcock, Janet (FDA/CDER)" (b) (6)  
> "Young, John" < (b) (6) "Colvis, Christine (NIH/NCATS) [E]" (b) (6)  
> "Desrosiers, Betsy" (b) (6) > "Eric Hughes" (b) (6)  
(b) (6) "Jansen, Kathrin" (b) (6) > "Kurilla, Michael (NIH/NCATS) [E]" < (b) (6)  
> "Lowy, Douglas (NCI)" < (b) (6) "Read, Sarah (NIH/NIAID) [E]" (b) (6)  
< (b) (6) "Young, John" (b) (6)  
**Cc:** "Bianchi, Diana (NIH/NICHD) [E]" (b) (6) "Byrnes, Noni (NIH/CSR) [E]" (b) (6)  
< (b) (6) [ih.gov](#)> "Glass, Roger (NIH/FIC) [E]" < (b) (6) "Hodes, Richard (NIH/NIA) [E]" (b) (6)  
< (b) (6) "Koob, George (NIH/NIAAA) [E]" < (b) (6) "Koroshetz, Walter (NIH/NINDS) [E]" < (b) (6)  
> "Langevin, Helene (NIH/NCCIH) [E]" (b) (6)



< (b) (6) "Norris, Andrea (NIH/CIT) [E]" < (b) (6) "Perez-Stable, Eliseo (NIH/NIMHD) [E]" (b) (6) , "Rodgers, Griffin (NIH/NIDDK) [E]" < (b) (6) "Schwetz, Tara (NIH/OD) [E]" < (b) (6) "Sharpless, Norman (NIH/NCI) [E]" < (b) (6) "Tucci, Debara (NIH/NIDCD) [E]" (b) (6) , "Tumminia, Santa (NIH/NEI) [E]" (b) (6) > , "Volkow, Nora (NIH/NIDA) [E]" (b) (6) "Woychik, Rick (NIH/NIEHS) [E]" < (b) (6) "Adam, Stacey (FNIH) [T]" < (b) (6) "Alvarez, Rosa" < (b) (6) "Anderson, Margaret" < (b) (6) "Chen, Helen" < (b) (6) "Elsaid, Olivia" (b) (6) , "Gonzalez, Nina" < (b) (6) "James, Stephanie (FNIH) [T]" (b) (6) "Menetski, Joseph (FNIH) [T]" (b) (6) "Santos, Michael (FNIH) [T]" < (b) (6) "Stratton, Ben" (b) (6) , "Tolman, Brett" < (b) (6) "Tountas, Karen (FNIH) [T]" (b) (6) > , "Wachtel, Jonathan" (b) (6) > , "Wholley, David (FNIH) [T]" (b) (6) > , "Anderson, James (NIH/OD) [E]" (b) (6) "Burklow, John (NIH/OD) [E]" (b) (6) , "Castillejos, Carlos" (b) (6) "Culp, Michelle (NIH/OD) [E]" (b) (6) FNIH Central Account < (b) (6) "Freire, Maria (FNIH) [T]" < (b) (6) , "Gadbois, Ellen (NIH/OD) [E]" (b) (6) , "Wolinetz, Carrie (NIH/OD) [E]" (b) (6) "Burklow, John (NIH/OD) [E]" < (b) (6) "Gorman, Greta (FNIH) [T]" < (b) (6) "Hallett, Adrienne (NIH/OD) [E]" (b) (6) , "Meltzer, Abbey (FNIH) [T]" (b) (6) , "Myles, Renate (NIH/OD) [E]" < (b) (6) "Melencio, Cheryl (FNIH) [T]" < (b) (6)

**Subject:** [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

**Resent-From:** (b) (6)

[Use CAUTION when opening links/attachments]

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 2:30 PM to 4:00 PM Eastern U.S. time tomorrow, Wednesday July 29. I have also attached notes from our July 1 Leadership Team meeting as well as our last ACTIV EC meeting on July 15.

The Zoom meeting information is:

Join Zoom Meeting

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley  
Senior Vice-President, Research Partnerships  
Foundation for the National Institutes of Health

(b) (6)

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**From:** Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]  
**Sent:** 7/17/2020 6:47:58 PM  
**To:** Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]  
**CC:** Alvarez, Rosa Maria [ (b) (6) ]  
**Subject:** RE: ACTIV Preclinical full working group

Sorry Ashley, I will follow up with Rosa to make sure you are always on the list (good list, not bad list 😊 )

Joe

---

**From:** Parker, Ashley (NIH/OD) [E] < (b) (6) >  
**Sent:** Friday, July 17, 2020 2:43 PM  
**To:** Menetski, Joseph (FNIH) [T] < (b) (6) >  
**Subject:** RE: ACTIV Preclinical full working group

Hi Joe,

Following up to let you know I did not receive the calendar invites to the preclinical subgroup meetings. I hope to be included soon.

Thank you,  
Ashley

---

**From:** Menetski, Joseph (FNIH) [T] < (b) (6) >  
**Sent:** Wednesday, July 8, 2020 2:51 PM  
**To:** Parker, Ashley (NIH/OD) [E] < (b) (6) >  
**Subject:** RE: ACTIV Preclinical full working group

Will do. I have sent a note to Rosa Alvarez to make sure you are added to the subgroups.

Joe

---

**From:** Parker, Ashley (NIH/OD) [E] < (b) (6) >  
**Sent:** Wednesday, July 8, 2020 1:52 PM  
**To:** Menetski, Joseph (FNIH) [T] < (b) (6) >  
**Subject:** RE: ACTIV Preclinical full working group

Thanks, Joe! Can you also please add me to the preclinical subgroup meetings?

Ashley

---

**From:** Menetski, Joseph (FNIH) [T] < (b) (6) >  
**Sent:** Wednesday, July 8, 2020 1:50 PM  
**To:** (b) (6) ; Hild, Sheri (NIH/OD) [E] < (b) (6) >  
(b) (6) ;  
(b) (6) Baric, Ralph (b) (6) < (b) (6) >  
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] < (b) (6) > ; Colvis, Christine (NIH/NCATS) [E] < (b) (6) > ; Hewitt, Judith (NIH/NIAID) [E] < (b) (6) > ; Deming, Damon



(FDA/CDER) (b) (6) Parker, Ashley (NIH/OD) [E]  
 (b) (6) Adams, Peter (OS/ASPR/BARDA)  
 (b) (6) >; Rao, Srinivas (b) (6) ; Qashu, Felicia (NIH/OD) [E]  
 (b) (6) Tomas Cihlar (b) (6) ; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID  
 (USA) (b) (6) >; Punturieri, Antonello (NIH/NHLBI) [E] (b) (6) >; Charette, Marc  
 (NIH/NHLBI) [E] (b) (6) >; Fessel, Josh (NIH/NHLBI) [E] (b) (6)  
 Cc: Diamond, Michael (b) (6) ; Austin, Christopher (NIH/NCATS) [E] (b) (6) >; Florence,  
 Clint (NIH/NIAID) [E] (b) (6) ; Simon, Dina (NIH/OD) [C] < (b) (6) ; Wholley, David (FNIH)  
 [T] (b) (6) >; Melencio, Cheryl (FNIH) [T] (b) (6) >; Colvis, Christine (NIH/NCATS) [E]  
 (b) (6) ; Desrosiers, Betsy (b) (6) ; Hughes, Eric  
 (b) (6) ; Jansen, Kathrin (b) (6) ; Kurilla, Michael (NIH/NCATS) [E]  
 (b) (6) ; Lowy, Douglas (NCI) < (b) (6) ; Read, Sarah (NIH/NIAID) [E] (b) (6)  
 Tountas, Karen (FNIH) [T] (b) (6) ; Santos, Michael (FNIH) [T] (b) (6) ; Adam, Stacey (FNIH) [T]  
 (b) (6) ; James, Stephanie (FNIH) [T] (b) (6) ; Alvarez, Rosa Maria (b) (6)  
 Kim, Elizabeth < (b) (6) ; Tolman, Brett < (b) (6) ; Wachtel, Jonathan  
 (b) (6) >; Prabhavathi Fernandes (b) (6) ; Rose Li  
 (b) (6) >; Dana Carluccio (b) (6) >; Lagos, Enrique (NIH/NCATS) [E]  
 < (b) (6) ; Jonson, Samantha (NIH/NCATS) [E] (b) (6) >; Gonzalez, Nina  
 (b) (6) ; Burrus-Shaw, Cyndi (NIH/OD) [E] (b) (6) >; Rodriguez, Robin D  
 (b) (6) ; Dave Frankowski (b) (6) >; Baric, Toni C  
 (b) (6) >; Lowy, Douglas (NIH/NCI) [E] (b) (6) ; Nancy Haigwood  
 (b) (6) ; Stratton, Benjamin (b) (6) ; Gadbois, Ellen (NIH/OD) [E]  
 (b) (6) ; Anderson, James (NIH/OD) [E] < (b) (6)

**Subject:** ACTIV Preclinical full working group

Dear Preclinical Working group and attendees,

I apologize for not providing the minutes from last week's meeting. Here they are for your review.

Sincerely,  
 Joe

Joseph P. Menetski Ph.D.  
 Associate Vice President, Research Partnerships  
 Foundation for the National Institutes of Health

(b) (6) | [fnih.org](https://fnih.org)  
 11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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**From:** Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]  
**Sent:** 1/12/2021 9:59:03 PM  
**To:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Carter, Kara [ (b) (6) Cavaleri, Marco (b) (6) ; Cihlar, Tomas (b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [ (b) (6) Culp, Michelle (NIH/OD) [E] [michelle.cu (b) (6) Victoria Davey [ (b) (6) ]; Disbrow, Gary (OS/ASPR/BARDA) [ (b) (6) Dolsten, Mikael [ (b) (6) Erbeling, Emily (NIH/NIAID) [E] [ (b) (6) Erck, Stan [ (b) (6) Fauci, Anthony (NIH/NIAID) [E] [ (b) (6) Gadbois, Ellen (NIH/OD) [E] [ (b) (6) Gibbons, Gary (NIH/NHLBI) [E] [ga (b) (6) Hudson, Thomas [ (b) (6) James, Stephanie (FNIH) [T] (b) (6) ; Johnson, Robert (OS/ASPR/BARDA) [ (b) (6) Kramer, Lynn [ (b) (6) Lane, Cliff (NIH/NIAID) [E] [ (b) (6) Lepore, John [john.j. (b) (6) Marks, Peter (FDA/CBER) [ (b) (6) Mascola, John (NIH/VRC) [E] [ (b) (6) ]; Meeker, David [ (b) (6) Menetski, Joseph (FNIH) [T] (b) (6) ; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [ (b) (6) Pandya, Hitesh [ (b) (6) ]; Pao, William [ (b) (6) Parker, Ashley (NIH/OD) [E] [ (b) (6) Perlmutter, Roger [ (b) (6) Plenge, Robert [ (b) (6) Plump, Andy [ (b) (6) Reese, David [ (b) (6) Rouse, Doris [ (b) (6) ; Santos, Michael (FNIH) [T] [ (b) (6) Skovronsky, Daniel [ (b) (6) ; Stein, Peter (FDA/CDER) [ (b) (6) Stoffels, Paul [ (b) (6) Tabak, Lawrence (NIH/OD) [E] [ (b) (6) ]; Talley, Michael [ (b) (6) Tsai, John [ (b) (6) Vessey, Rupert [ (b) (6) ]; Virgin, Skip [ (b) (6) Wholley, David (FNIH) [T] (b) (6) Young, John [ (b) (6) Colvis, Christine (NIH/NCATS) [E] (b) (6) ; Desrosiers, Betsy [ (b) (6) Eric Hughes [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] (b) (6) Lowy, Douglas (NCI) (b) (6) ]; Read, Sarah (NIH/NIAID) [E] [ (b) (6) Adam, Stacey (FNIH) [T] [ (b) (6) Margaret Anderson [ (b) (6) Appell, Evar (b) (6) ; Chen, Helen [ (b) (6) ]; Connelly, Sarah [ (b) (6) Gonzalez, Nina [ningonza (b) (6) Hawk, Harrison [ (b) (6) ]; Mendelson, Jesse [ (b) (6) Nasr, Hana [ (b) (6) Sorosa, Alex [ (b) (6) Stratton, Benjamin (b) (6) ; btolman [ (b) (6) Wachtel, Jonathan [ (b) (6) ]; Anderson, James (NIH/OD) [E] [ (b) (6) ]; Burklow, John (NIH/OD) [E] [ (b) (6) Carluccio, Dana [ (b) (6) Castillejos, Carlos [ (b) (6) FNIH Central Account [ (b) (6) Hallett, Adrienne (NIH/OD) [E] [ (b) (6) ]; Lumsden, Joanne (NIH/NCATS) [C] [ (b) (6) Myles, Renate (NIH/OD) [E] [ (b) (6) Wolinetz, Carrie (NIH/OD) [E] [carrie. (b) (6) ]; Meltzer, Abbey (FNIH) [T] [ (b) (6) Embry, Alan (NIH/NIAID) [E] [ (b) (6) Venkayya, Rajeev [ (b) (6) Rutter, Joni (NIH/NCATS) [E] (b) (6) ; Cwalina, Alex [ (b) (6) Milan, Marina (FNIH) [T] [ (b) (6) Brodd, Lauren (NIH/OD) [E] [ (b) (6) Bancel, Stephane [ (b) (6) Pangalos, Mene [ (b) (6) ; Paul, Steve (b) (6) ; Rachel Ramoni [ (b) (6) Reed, John [ (b) (6) Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]  
**CC:** Austin, Sarah (NIH/NIAID) [E] (b) (6) ; Barasch, Kimberly (NIH/NIAID) [C] [ (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] (b) (6) ]; Carver, Trea (NIH) [C] [trea. (b) (6) Caulfied, Anita [ (b) (6) Coan, Amanda [ (b) (6) ]; Conrad, Patricia (NIH/NIAID) [E] (b) (6) Dimishkov, Roxanne (NIH/NHLBI) [C] [ (b) (6) ]; Edl, Susan (b) (6) Fuhrer, Nicole [ (b) (6) ; Giorgi, Sara (b) (6) ; Hoban, Michelle [ (b) (6) Hoffstetter, Renata (FNIH) [T] [ (b) (6) Iberdemaj, Vaide [vaide. (b) (6) Jenkins, Christine S. [ (b) (6) Lever, Susan (b) (6) Magbie-Robinson, Kim (NIH/OD) [C] [ (b) (6) Martin, Melisa [ (b) (6) McManus, Ayanna (NIH/OD) [E] [ (b) (6) Minnich, Beth [ (b) (6) Perala, Mie (b) (6) Protasiewicz, Ann [ (b) (6) Riffin, Mary [ (b) (6) Ripley, Nadege



(b) (6) Schuster, Donna (b) (6) Sepulveda, Dorina (FNIH) [T]  
(b) (6) Simon, Dina (NIH/OD) [C] (b) (6) Suhana, Tina (NIH/VRC) [E]  
(b) (6) ]; Thomas, Ashley (FDA/CDER) (b) (6) ]; Wood, Gretchen (NIH/OD) [E]  
(b) (6) Togashi, Mieko (NIH/NCI) [E] (b) (6) .gov]; Underwood, Nancy  
(b) (6) Zottoli, Jessica [Jessica. (b) (6) Hughes, Karen (NIH/OD) [E]  
(b) (6) Regan, Donna M (b) (6) Plenge, Robert (b) (6)  
Vessey, Rupert (b) (6) Burke, Leslie [lesl (b) (6) Moghiminia, Mahtab  
(NIH/NCATS) [E] (b) (6) Lowy, Douglas (NIH/NCI) [E] (b) (6) ]; Bell, Julie  
(b) (6) Riccobene, Kim (b) (6)

**Subject:** ACTIV Leadership Team Call #16

**Location:** <https://fnih.zoom.us/> (b) (6)

**Start:** 5/28/2021 1:00:00 PM

**End:** 5/28/2021 2:30:00 PM

**Show Time As:** Busy

**Required Attendees:** Melencio, Cheryl (FNIH) [T]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Davey, Victoria; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Nasr, Hana; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Meltzer, Abbey (FNIH) [T]; Embry, Alan (NIH/NIAID) [E]; Venkayya, Rajeev; Rutter, Joni (NIH/NCATS) [E]; Cwalina, Alex; (b) (6) Brodd, Lauren (NIH/OD) [E]

**Optional Attendees:** Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [E]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfield, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lever, Susan; Magbie-Robinson, Kim (NIH/OD) [C]; Martin, Melissa; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggan, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Hughes, Karen (NIH/OD) [E]; Regan, Donna M; Plenge, Robert; Vessey, Rupert; Burke, Leslie; Moghiminia, Mahtab (NIH/NCATS) [E]; Lowy, Douglas (NIH/NCI) [E]

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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 6/20/2020 3:51:18 PM  
**To:** Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan\_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [ (b) (6) Eisner, Mark [ (b) (6) Gottesdiener, Keith [ (b) (6) Hughes, Eric [ (b) (6) Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [ (b) (6) LaVange, Lisa [ (b) (6) Levy, Elliot [ (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaa06ebd70-parkeras]; Patel, Naimish [naimish.patel@sanofi.com]; Peppercorn, Amanda [ (b) (6) Poole, Mike [ (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collis]; Amanda Peppercorn [ (b) (6) Garner, Carl [ (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetz]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [ (b) (6)]



CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [ (b) (6) Biggs, Mary [ (b) (6) Butcher, Tina [ (b) (6) Demarcus [ (b) (6) Macone, Erin [ (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [ (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [ (b) (6) Tolman, Brett [ (b) (6) Alvarez, Rosa [ (b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [ (b) (6) Rose Li Central Account [ (b) (6) Anderson, Margaret [ (b) (6) Lucas Smalldon [ (b) (6) Stratton, Benjamin [ (b) (6) [ (b) (6) Mollica, Linda /US [ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [ (b) (6) Wung, Peter /US [ (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]

**Subject:** ACTIV TX-Clinical Working Group Meeting #11

**Attachments:** 2020-06-18\_TX-Clinical\_WG\_Meeting\_Summary.pdf; ACTIV\_TX-Clinical\_Working Group Meeting Guide\_20200618.pdf

Dear ACTIV TX-Clinical Working Group,

Thank you all again for a great meeting this week. In follow-up, please find attached the formal summary for our meeting on June 18, 2020.

In addition, in response to the question on the agents for the ACTIV-4 trial, the NHLBI team has provided the following information:

*Currently we consider the following:*

**For pre-hospital trial:**

- Adaptive design study of placebo control, anti-platelets (for example dipyridamole), direct anti-coagulant (for example apixaban). Arms may be dropped for futility and/or adaptively combined along the study.

**In-hospital trial:**

- *Adaptive design of UF and LMW heparin in low prophylaxis dose and high therapeutic dose with and without anti-platelets (for example dipyridamole).*

**Post-hospitalization trial:**

- *Adaptive design study to investigate continuation of LMWH, anti-platelets (dipyridamole), direct anti-coagulant (for example rivaroxaban) after 3 weeks of post-hospital discharge with LMWH treatment. Arms may be dropped for futility and/or adaptively combined along the study.*

Also, for those, interested in getting access to the CTC WG Dashboard for network and sites please email me and I can send you the details on the information that you will need to send to our team to get access.

Thanks,  
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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**From:** Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]  
**Sent:** 6/15/2020 5:04:44 PM  
**To:** (b) (6); (b) (6); Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6); (b) (6); (b) (6); (b) (6); (b) (6); Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6); Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7adadfbcd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6); (b) (6); (b) (6); Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [ (b) (6); Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [ (b) (6); Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [ (b) (6); Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]  
**CC:** Diamond, Michael [ (b) (6); Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6); Hughes, Eric [ (b) (6); Jansen, Kathrin [ (b) (6); Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [ (b) (6) Kim, Elizabeth [ (b) (6) Tolman, Brett [ (b) (6) Wachtel, Jonathan [ (b) (6) Prabhavathi Fernandes [ (b) (6) Rose Li [ (b) (6) Dana Carluccio [ (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [ (b) (6) Dave Frankowski [ (b) (6) Baric, Toni C [ (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [ (b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]

**Subject:** RE: ACTIV Preclinical full working group  
**Attachments:** 2020-06-10\_Preclinical\_WG\_Summary\_F2.docx

Dear Preclinical working group members and attendees,

Please find the minutes from last weeks meeting attached. Feel free to contact me if you have any questions.

Best regards,  
Joe

-----Original Appointment-----

**Subject:** ACTIV Preclinical full working group  
**When:** Wednesday, June 10, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).  
**Where:** <https://fnih.zoom.us>, (b) (6)

Changing time for preclinical WG

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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 5/22/2020 2:30:56 AM  
**To:** Eric Hughes [ (b) (6) ]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [ (b) (6) .com]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [ (b) (6) ]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [ (b) (6) ]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [ (b) (6) ]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [ (b) (6) ]; Keith Gottesdiener [ (b) (6) ]; Elliott Levy [ (b) (6) ]; Wung, Peter /US [ (b) (6) ]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [ (b) (6) ]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]  
**CC:** Elizabeth Kim [ (b) (6) ]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [ (b) (6) ]; Salathin, Carla [ (b) (6) ]; (b) (6) ; (b) (6) ; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [ (b) (6) ]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [ (b) (6) ]; Chen, Helen Q. [ (b) (6) ]  
**Subject:** ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #13  
**Location:** <https://fnih.zoom.us> (b) (6)  
**Start:** 5/28/2020 4:00:00 PM  
**End:** 5/28/2020 5:00:00 PM  
**Show Time As:** Tentative

**Required Attendees:** Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]  
**Optional Attendees:** Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; (b) (6) ; (b) (6) ; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] (b) (6) ; Rose Li Central Account; Chen, Helen Q.

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**From:** Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]  
**Sent:** 9/25/2020 4:57:20 PM  
**To:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [ (b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Pao, William [ (b) (6) Plump, Andrew [ (b) (6) Stoffels, Paul [ (b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [ (b) (6)  
**CC:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mendelson, Jesse [ (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Perala, Mie



[ (b) (6) Protasiewicz, Ann [ (b) (6) Riccobene, Kim  
 [ (b) (6) Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 [ (b) (6) Castillejos, Carlos [ (b) (6) Culp, Michelle (NIH/OD) [E]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 [ (b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Sepulveda, Dorina (FNIH)  
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD)  
 [C] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Tajalli, Ada (NIH/OD) [E]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4fd4747b0d954e27855c241b28562547-tajallian]; Gorman, Greta (FNIH) [T]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Meltzer, Abbey (FNIH)  
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Togashi, Miekko (NIH/NCI)  
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Underwood, Nancy  
 [ (b) (6) Zottoli, Jessica [ (b) (6)

**Subject:** ACTIV EC & Working Group Co-Chair Meeting

**Location:** <https://fnih.zoom>. (b) (6)

**Start:** 11/4/2020 3:00:00 PM

**End:** 11/4/2020 4:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John

**Optional Attendees:** Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Appell, Evan; Chen, Helen; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; Culp, Michelle (NIH/OD) [E]; FNIH Central Account; Freire, Maria (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hughes, Karen (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Tajalli, Ada (NIH/OD) [E]; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Togashi, Miekko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica

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**From:** (b) (6) [ (b) (6) ]  
**Sent:** 3/2/2021 7:55:05 PM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]  
**Subject:** Re: [EXTERNAL] a few follow ups

All good then

Let's consider to catch up 1/1 in a couple of weeks or when you find it helpful on the many topics

(b) (6)

Sent from my iPhone

On Mar 2, 2021, at 14:36, Collins, Francis (NIH/OD) [E] < (b) (6) > wrote:

Yes, we also delighted to push forward on the protease inhibitors!

And yes also to design of vaccines against B.1.351 and possible need for boosts. I'm just hoping there's not an even worse variant lurking out there. Come on people, get vaccinated!

Best, Francis

---

**From:** (b) (6) (b) (6)  
**Sent:** Tuesday, March 2, 2021 9:52 AM  
**To:** Collins, Francis (NIH/OD) [E] < (b) (6) >  
**Subject:** Re: [EXTERNAL] a few follow ups

Francis

I was thrilled to hear that ACTIV approved our IV and ORAL protease inhibitor (PI) pending phase 1 data on oral PI

Confidentially, we just dosed a handful of individuals w our oral PI drug this week and are progressing rapidly. Hope to soon have the data we need to start the P2/3 w ACTIV

Let's stay in touch

Anything to catch up on on the next steps w Covid vaccines. Seems like Moderna-NIH and Pfizer are running similar studies to assess third boost and variant vaccine etc

(b) (6)

Sent from my iPhone

On Feb 15, 2021, at 19:09, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Hi (b) (6)

Very interesting presentation, and a great opportunity to work together on the next steps. Let's do this!

Best, Francis

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**From:** (b) (6) >  
**Sent:** Monday, February 15, 2021 3:34 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6) >  
**Subject:** Re: [EXTERNAL] a few follow ups

Dear Francis

Thanks for organizing that we all could come together today on a holiday to swiftly discuss the protease inhibitor program

We are very excited to progress the discussed partnership

Best

(b) (6)

Sent from my iPhone

On Feb 13, 2021, at 11:49, Collins, Francis (NIH/OD) [E]  
(b) (6) wrote:

Though it's a federal holiday, Monday might also be a possibility – I'd be fine with that.

Francis

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Saturday, February 13, 2021 11:17 AM  
**To:** (b) (6)  
**Cc:** Fauci, Anthony (NIH/NIAID) [E] (b) (6) Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)>; Wood, Gretchen (NIH/OD) [E] (b) (6); Barasch, Kimberly (NIH/NIAID) [E] (b) (6); Conrad, Patricia (NIH/NIAID) [E]  
**Subject:** RE: [EXTERNAL] a few follow ups

Hi (b) (6)

I've discussed with Tony, and we are very interested in meeting with you and your team. I'd like Tony, Cliff Lane, David Wholley, and me to join, and you can decide which of the Pfizer team would be most essential.



I'm looping in Gretchen Wood who can work with your Pfizer team to find a good time for this. Tuesday may be a challenge, but all of us will seek to move calendars around if necessary.

Best, Francis

---

**From:** (b) (6)  
**Sent:** Friday, February 12, 2021 2:32 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** Re: [EXTERNAL] a few follow ups

Francis

If you prefer a smaller group , I am pleased also to present the protease drug highlights myself and John together with our CEO Albert Bourla from Pfizer to meet the three of you

Best

(b) (6)

Sent from my iPhone

On Feb 12, 2021, at 14:16, (b) (6)  
(b) (6) wrote:

Dear Francis

I and our Pfizer CEO Albert Bourla just reviewed the clinical plans from our protease inhibitor team . We also assessed manufacturing needs (for EUA) to possibly plan for success with time lines for potential EUA already in 2021 or early 2022 (pending good data of course).

We would enjoy as you suggested below meeting you , Tony and David as soon as possible - maybe Tuesday next week (Monday is holiday ) to discuss how we can work together on our IV and ORAL pan-Corona virus protease inhibitor (Pi) drugs .

In this time of SARSCov2 viral evolution , they seems like a drug class with great promise .

We have submitted the IV PI drug to ACTIV with positive reception . We are planning to submit the oral PI drug to ACTIV on Wednesday next week .

Albert will join me in the meeting with you. If you want to have some more detailed background science on the drugs , I was thinking to bring in our two key scientist leaders in this area eg Liesa Anderson and Charlotte

Allerton . Liesa participated in ACTIV since the start within therapeutics related work streams .

Look forward to your response

Best  
(b) (6)

Sent from my iPhone

On Feb 11, 2021, at 05:26, Collins,  
Francis (NIH/OD) [E]

(b) (6) > wrote:

Hi (b) (6)

Thanks for quick response to my message – and wow, the progress on the oral anti-protease is fantastic! In the face of rising concerns about viral variants in the spike protein, the efficacy against all coronaviruses is extremely encouraging – will this even cure the common cold? 😊 I am sure the ACTIV team would be ready to move quickly to slot this into ACTIV-2/3, pending the results of your phase 1 SAD-MAD studies. Considering possible combination therapies could also be a very appealing next step.

Let me know when you are ready to discuss – I'd like to bring Tony Fauci and David Wholley into that conversation soon.

Best, Francis

---

**From:** (b) (6)

**Sent:** Wednesday, February 10, 2021  
8:36 AM

**To:** Collins, Francis (NIH/OD) [E]

< (b) (6) >

**Subject:** Re: [EXTERNAL] a few follow ups

Hi Francis

Good that you try to correct NYT article  
but TIME paper was great

The exciting piece w the antiviral  
protease inhibitor (PI) drugs is that they  
are pan-corona virus active w potential  
as a drug for any new pandemic  
coronavirus. They also will inhibit all  
presently known SARSCov2 mutant  
variants that mainly affect SPIKE

**Confidential update**

(b) (4)





(b) (4)

(b) (6)

Sent from my iPhone

On Feb 10, 2021, at  
06:33, Collins, Francis  
(NIH/OD) [E]

(b) (6)

wrote:

Hi (b) (6)

Just checking in. First,  
thanks for your kind  
words that were  
quoted in the TIME  
magazine profile – very  
much appreciated!

Second, I have been  
distressed by the  
uninformed  
characterization of the  
ACTIV efforts on  
therapeutics in the New  
York Times article ten  
days ago by Carl  
Zimmer, and a more  
recent OpEd from Zeke  
Emanuel et al. The  
TIME article gave a  
much more accurate  
depiction, and I hope

that was noticed. My staff and I are working in other ways to correct the record on this – including an upcoming New Yorker article and 60 Minutes segment that will be much more positive!

Third, I am glad to see positive momentum in moving forward with the Pfizer anti-protease therapeutic through ACTIV. I hear good things about PF-07304814, and the potential for entering this into the ACTIV-3 trial in the near future. Of course I'm also intensely curious about your progress with an oral anti-protease, since that could be a true game-changer for this pandemic – and an advance desperately needed at a time where new SARS-CoV-2 viral variants are causing a lot of concern. Anything you can tell me about progress there?

All the best, Francis

---

**From:** Heatherington, Anne [ (b) (6) ]  
**Sent:** 7/1/2020 12:54:44 AM  
**To:** Plump, Andrew [ (b) (6) ]  
**CC:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]  
**Subject:** Re: Data Sharing Slide for ACTIV LT Meeting  
**Flag:** Follow up

Thanks David. One additional point to note is that we now have clearly assigned points of contact between COVID R&D (Sandeep Menon, Pfizer) and NIH (Michelle Culp) to ensure a smooth relationship.

Anne

On Jun 30, 2020, at 7:34 PM, Plump, Andrew < (b) (6) > wrote:

Hi David - Yes, I will be at tomorrow's meeting and can speak to these points together with Francis.

Cheers,  
Andy

Sent from my iPad

On Jun 30, 2020, at 7:33 PM, Wholley, David (FNIH) [T] < (b) (6) > wrote:

Be advised that this email came from outside Takeda / お知らせ：社外から送信されたメールです

Hi Andy—

Just a heads up that on tomorrow's Leadership Team call (which I see you have accepted on your calendar) we will be addressing as an action item the follow up on data sharing discussions. We've prepared the following reasonably high level slide that you and Francis could talk to. Thanks, David

<Update on Data Sharing\_Slide for ACTIV LT Meeting.pptx>

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**From:** Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]  
**Sent:** 5/2/2020 2:29:00 PM  
**To:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]  
**CC:** Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]  
**Subject:** RE: Update on other COVID "master protocol" efforts

This is indeed a cause for serious concern. See my note about a conversation I had with Gary Gibbons yesterday, and the need to bring NHLBI back into the tent.

Do I need to have the same conversation with Walter Koroshetz?

FC

---

**From:** Wholley, David (FNIH) [T] <(b) (6)>  
**Sent:** Friday, May 1, 2020 7:12 PM  
**To:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Cc:** Tabak, Lawrence (NIH/OD) [E] <(b) (6)>  
**Subject:** Update on other COVID "master protocol" efforts

Hi Francis,

I sat in on several of the Working Group calls today and had my daily update with my team and one with Deloitte. I learned:

- The VA is working on a master protocol for COVID; Margaret Anderson thinks Mike Milken is behind this. Karen Tountas has arranged for our VA rep on the Clinical Trial Capacity Group, Victoria Davey, to set up a call with the VA MP folks and the ACTIV MP design Sub Group Stacey Adam is leading.
- From a presentation that Mike Poole of Gates Foundation gave us, their Tx Accelerator is arranging reasonably robust testing of many of the compounds we are looking to prioritize for ACTIV, including to our surprise mAbs. We still see daylight, but differentiation will be that much more challenging.
- NHLBI is actively designing an MP in their PETAL network for anticoagulants. Thanks to Cliff Lane, we are trying to get Amy Patterson to speak to Sarah Read and Stacey so we have some chance to decently align approaches.
- NINDS is both collaborating with NHLBI and running their own protocol using their SIREN network.

We cannot control what Milken and Gates do, but it is distressing to see efforts announced within NIH that more or less completely overlap and potentially compete for the same kinds of protocols and patients that ACTIV is attempting to address. It makes the partnership overall look disorganized. In fact one of our WG co-chairs used the chat feature on Zoom to comment on the side to one of my folks during a description of one of the other side NIH institute efforts that "this is like a circus—how do these people not talk to each other?"

This is not good. While you have my commitment that we will always do what we can to make sure we communicate to others in NIH the ACTIV plans, we are going to lose control of the public narrative overall if this continues. I think there is still time to address this; I would suggest a way be found to bring these other efforts together under the ACTIV banner and brand as soon as possible.

Regards,  
David

David Wholley  
Senior Vice-President, Research Partnerships  
Foundation for the National Institutes of Health  
(b) (6)

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**From:** Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]  
**Sent:** 1/12/2021 9:59:03 PM  
**To:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Carter, Kara [ (b) (6) Cavaleri, Marco (b) (6) ; Cihlar, Tomas (b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [ (b) (6) Culp, Michelle (NIH/OD) [E] (b) (6) Victoria Davey [ (b) (6) ]; Disbrow, Gary (OS/ASPR/BARDA) [ (b) (6) Dolsten, Mikael [ (b) (6) Erbeling, Emily (NIH/NIAID) [E] [ (b) (6) Erck, Stan [ (b) (6) Fauci, Anthony (NIH/NIAID) [E] [ (b) (6) Gadbois, Ellen (NIH/OD) [E] [ (b) (6) Gibbons, Gary (NIH/NHLBI) [E] (b) (6) Hudson, Thomas [ (b) (6) James, Stephanie (FNIH) [T] (b) (6) ; Johnson, Robert (OS/ASPR/BARDA) [ (b) (6) Kramer, Lynn [ (b) (6) Lane, Cliff (NIH/NIAID) [E] [ (b) (6) Lepore, John (b) (6) Marks, Peter (FDA/CBER) [ (b) (6) Mascola, John (NIH/VRC) [E] [ (b) (6) ]; Meeker, David [ (b) (6) Menetski, Joseph (FNIH) [T] (b) (6) ; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [ (b) (6) Pandya, Hitesh [ (b) (6) ]; Pao, William [ (b) (6) Parker, Ashley (NIH/OD) [E] [ (b) (6) Perlmutter, Roger [ (b) (6) Plenge, Robert [ (b) (6) Plump, Andy [ (b) (6) Reese, David [ (b) (6) Rouse, Doris (b) (6) ; Santos, Michael (FNIH) [T] [ (b) (6) Skovronsky, Daniel [ (b) (6) ; Stein, Peter (FDA/CDER) [ (b) (6) Stoffels, Paul [ (b) (6) Tabak, Lawrence (NIH/OD) [E] [ (b) (6) ]; Talley, Michael [ (b) (6) Tsai, John [ (b) (6) Vessey, Rupert [ (b) (6) ]; Virgin, Skip [ (b) (6) Wholley, David (FNIH) [T] [dwhol Young, John [ (b) (6) Colvis, Christine (NIH/NCATS) [E] (b) (6) ; Desrosiers, Betsy [ (b) (6) Eric Hughes [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [michael. Lowy, Douglas (NCI) (b) (6) ]; Read, Sarah (NIH/NIAID) [E] [ (b) (6) Adam, Stacey (FNIH) [T] [ (b) (6) Margaret Anderson [ (b) (6) Appell, Evan (b) (6) ; Chen, Helen [ (b) (6) ]; Connelly, Sarah [ (b) (6) Gonzalez, Nina (b) (6) Hawk, Harrison [ (b) (6) ]; Mendelson, Jesse [ (b) (6) Nasr, Hana [ (b) (6) Sorosa, Alex [ (b) (6) Stratton, Benjamin (b) (6) ; btolman [ (b) (6) Wachtel, Jonathan [ (b) (6) ]; Anderson, James (NIH/OD) [E] [ (b) (6) ]; Burklow, John (NIH/OD) [E] [ (b) (6) Carluccio, Dana [ (b) (6) Castillejos, Carlos [ (b) (6) FNIH Central Account [ (b) (6) Hallett, Adrienne (NIH/OD) [E] [ (b) (6) ]; Lumsden, Joanne (NIH/NCATS) [C] [ (b) (6) Myles, Renate (NIH/OD) [E] [ (b) (6) Wolinetz, Carrie (NIH/OD) [E] (b) (6) ]; Meltzer, Abbey (FNIH) [T] [ (b) (6) Embry, Alan (NIH/NIAID) [E] [ (b) (6) Venkayya, Rajeev [ (b) (6) Rutter, Joni (NIH/NCATS) [E] (b) (6) ; Cwalina, Alex [ (b) (6) Milan, Marina (FNIH) [T] [ (b) (6) Brodd, Lauren (NIH/OD) [E] [ (b) (6) Bancel, Stephane [ (b) (6) Pangalos, Mene [ (b) (6) ; Paul, Steve (b) (6) ; Rachel Ramoni [ (b) (6) Reed, John [ (b) (6) Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]  
**CC:** Austin, Sarah (NIH/NIAID) [E] (b) (6) ; Barasch, Kimberly (NIH/NIAID) [C] [ (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] (b) (6) ]; Carver, Trea (NIH) [C] [trea. (b) (6) Caulfied, Anita [ (b) (6) Coan, Amanda [ (b) (6) ]; Conrad, Patricia (NIH/NIAID) [E] [ (b) (6) Dimishkov, Roxanne (NIH/NHLBI) [C] [ (b) (6) ]; Edl, Susan (b) (6) Fuhrer, Nicole [ (b) (6) ; Giorgi, Sara (b) (6) ; Hoban, Michelle [ (b) (6) Hoffstetter, Renata (FNIH) [T] [ (b) (6) Iberdemaj, Vaide [vaide. (b) (6) Jenkins, Christine S. [ (b) (6) Lever, Susan [susan. (b) (6) Magbie-Robinson, Kim (NIH/OD) [C] [ (b) (6) Martin, Melisa [ (b) (6) McManus, Ayanna (NIH/OD) [E] [ (b) (6) Minnich, Beth [ (b) (6) Perala, Mie [mie.pera Protasiewicz, Ann [ (b) (6) Riffin, Mary [ (b) (6) Ripley, Nadege



(b) (6) Schuster, Donna [donna. Sepulveda, Dorina (FNIH) [T]  
(b) (6) Simon, Dina (NIH/OD) [C] (b) (6) Suhana, Tina (NIH/VRC) [E]  
(b) (6) ]; Thomas, Ashley (FDA/CDER) (b) (6) ]; Wood, Gretchen (NIH/OD) [E]  
(b) (6) Togashi, Mieko (NIH/NCI) [E] (b) (6) .gov]; Underwood, Nancy  
(b) (6) Zottoli, Jessica [Jessica. (b) (6) Hughes, Karen (NIH/OD) [E]  
(b) (6) Regan, Donna M (b) (6) Plenge, Robert (b) (6)  
Vessey, Rupert (b) (6) Burke, Leslie [lesl (b) (6) Moghiminia, Mahtab  
(NIH/NCATS) [E] (b) (6) Lowy, Douglas (NIH/NCI) [E] (b) (6) ]; Bell, Julie  
(b) (6) Riccobene, Kim (b) (6)

**Subject:** ACTIV Leadership Team Call #16

**Location:** <https://fnih.zoom.us> (b) (6)

**Start:** 5/28/2021 1:00:00 PM

**End:** 5/28/2021 2:30:00 PM

**Show Time As:** Busy

**Required Attendees:** Melencio, Cheryl (FNIH) [T]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Davey, Victoria; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Nasr, Hana; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Meltzer, Abbey (FNIH) [T]; Embry, Alan (NIH/NIAID) [E]; Venkayya, Rajeev; Rutter, Joni (NIH/NCATS) [E]; Cwalina, Alex; (b) (6) Brodd, Lauren (NIH/OD) [E]

**Optional Attendees:** Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [E]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfield, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lever, Susan; Magbie-Robinson, Kim (NIH/OD) [C]; Martin, Melissa; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggan, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Hughes, Karen (NIH/OD) [E]; Regan, Donna M; Plenge, Robert; Vessey, Rupert; Burke, Leslie; Moghiminia, Mahtab (NIH/NCATS) [E]; Lowy, Douglas (NIH/NCI) [E]

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**From:** Anderson, James (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=73143D1860BC42458BE254CA21573B23-ANDERSONJM]  
**Sent:** 5/13/2020 11:23:17 AM  
**To:** Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]  
**Subject:** FW: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time  
**Attachments:** Need for NHP planning coordination process 5-12-2020.docx

Larry,

My responsibilities start earlier today than I thought. Attach is a summary of where we are with planning for NHP use for COVID research. Feel free to paraphrase at today's Exec Comm meeting and tomorrow's ICD meeting.

We plan to make the admin supplements to the NPRCs (\$30M from Hugh) require that the NPRCs develop a coordinating center to interact with ACTIV. Interaction with the NIAID resources still requires coordination.

Thanks for your help.

Jim

---

**From:** Wholley, David (FNIH) [T] <(b) (6)>  
**Sent:** Tuesday, May 12, 2020 9:57 PM  
**To:** Collins, Francis (NIH/OD) [E] <(b) (6)> Dolsten, Mikael <(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)> Pao, William <(b) (6)> Stoffels, Paul [JJCUS] <(b) (6)> Woodcock, Janet (FDA/CDER) <(b) (6)> Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Desrosiers, Betsy <(b) (6)> Hughes, Eric <(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E] <(b) (6)> Lowy, Douglas (NIH/NCI) [E] <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Young, John <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Anderson, James (NIH/OD) [E] <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Wolf-Rodda, Julie (FNIH) [T] <(b) (6)> Gonzalez, Nina <(b) (6)>  
**Cc:** Melencio, Cheryl (FNIH) [T] <(b) (6)> Wood, Gretchen (NIH/OD) [E] <(b) (6)>  
**Subject:** Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time  
**Importance:** High

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:  
Please see attached the agenda for our meeting tomorrow morning (via Zoom) and a copy of the letter from the Therapeutics- Clinical Working Group you received earlier today, for our discussion.

Please let Joe Menetski or Cheryl Melencio know if you are having any problems connecting. I look forward to a productive meeting.



Regards,

David

David Wholley  
Senior Vice-President, Research Partnerships  
Foundation for the National Institutes of Health

(b) (6)

[fnih.org](http://fnih.org)

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---

**From:** Amanda Peppercorn [ (b) (6) ]  
**Sent:** 5/14/2020 3:59:41 PM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]  
**CC:** Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]  
**Subject:** RE: Time sensitive: Making your ACTIV Participation Public

Yes, you may use my name.

Best,

*Amanda*

Amanda Peppercorn, M.D.  
GSK Research & Development  
mobile (b) (6)  
email (b) (6)

---

**From:** Collins, Francis (NIH/OD) [E] < (b) (6) >  
**Sent:** Thursday, May 14, 2020 11:00 AM  
**To:** Collins, Francis (NIH/OD) [E] < (b) (6) >  
**Cc:** Myles, Renate (NIH/OD) [E] < (b) (6) >; Meltzer, Abbey (FNIH) [T] < (b) (6) >; Wholley, David (FNIH) [T] < (b) (6) >  
**Subject:** Time sensitive: Making your ACTIV Participation Public

EXTERNAL

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,  
Francis

Francis S. Collins, MD, PhD  
NIH Director

COLL0000009500-2516970

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**From:** Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]  
**Sent:** 12/22/2020 4:45:56 PM  
**To:** Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijs]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m; (b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7adfcdb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) ; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [ (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [ (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; I (b) (6) (b) (6)  
**CC:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [ (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria



[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [ (b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [ (b) (6) Diamond, Michael [ (b) (6) Rose Li [ (b) (6) Dana Carluccio [ (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [ (b) (6) Dave Frankowski [ (b) (6) antoinette\_baric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb6b844cf]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen [ (b) (6) (b) (6) Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; (b) (6) Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent Lloyd [ (b) (6) (b) (6)

**Subject:** ACTIV Preclinical full working group

**Attachments:** Untitled Attachment

**Location:** https://fnih.zoom. (b) (6)

**Start:** 4/22/2020 2:00:00 PM

**End:** 4/22/2020 3:00:00 PM

**Show Time As:** Tentative

**Recurrence:** Weekly  
every Wednesday from 10:00 AM to 11:00 AM

**Required Attendees:** Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6) (b) (6)

(b) (6) (b) (6) (b) (6) (b) (6);  
(b) (6) (b) (6) ccolvis@mail.nih.gov; (b) (6)  
(b) (6) (b) (6) (b) (6) (b) (6) Parker,  
Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter  
(OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM  
USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E];  
(b) (6)

**Optional Attendees:** Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha

(NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; (b) (6) Connolly, Sarah; (b) (6) .com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; (b) (6)

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(b) (6) US (Houston)

Meeting ID: (b) (6)

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Find your local number: <https://fnih.> (b) (6)



**From:** Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]  
**Sent:** 4/30/2020 2:18:13 PM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]  
**Subject:** FW: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

**Flag:** Follow up

FYI, something to think about.

---

**From:** Bozzette, Sam (NIH/NCATS) [E] <(b) (6)>  
**Sent:** Thursday, April 30, 2020 9:19 AM  
**To:** Adam, Stacey (FNIH) [T] <(b) (6)> Butterson, Joan <(b) (6)> Collins, Sylva (FDA/CDER) <(b) (6)> Judy Currier <(b) (6)> De Claro, R. Angelo (FDA/CDER) <(b) (6)> Mark Eisner <(b) (6)> Keith Gottesdiener <(b) (6)> Eric Hughes <(b) (6)> LaVange, Lisa M <(b) (6)> Elliott Levy <(b) (6)> Sandeep Menon <(b) (6)> Amanda Peppercorn <(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Amanda Peppercorn <(b) (6)> Price, Dionne (FDA/CDER) <(b) (6)> Rubin, Daniel B. (FDA/CDER) <(b) (6)> Shen, Yuan Li (FDA/CDER) <(b) (6)> Farley, John (FDA/CDER) <(b) (6)> Goff, David (NIH/NHLBI) [E] <(b) (6)> Vincent, Michael <(b) (6)>  
**Cc:** Mary Biggs <(b) (6)> Demarcus <(b) (6)> Macone, Erin <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> Wachtel, Jonathan <(b) (6)> Elizabeth Kim <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Butcher, Tina <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)> Wung, Peter /US <(b) (6)> Qashu, Felicia (NIH/OD) [E] <(b) (6)> Stratton, Benjamin <(b) (6)>  
**Subject:** Re: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Good morning all:

It would seem that our active control arm had been identified. Should we get in the queue with Gilead sooner rather than later - or have we already reached out to them?

S

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**From:** "Adam, Stacey (FNIH) [T]" <(b) (6)>  
**Date:** Thursday, April 23, 2020 at 8:31:00 PM  
**To:** "Bozzette, Sam (NIH/NCATS) [E]" <(b) (6)>, "Butterson, Joan" <(b) (6)>, "Collins, Sylva (FDA/CDER)" <(b) (6)>, "Judy Currier" <(b) (6)>, "De Claro, R. Angelo (FDA/CDER)" <(b) (6)>, "Mark Eisner" <(b) (6)>, "Keith Gottesdiener" <(b) (6)>, "Eric Hughes" <(b) (6)>, "LaVange, Lisa M" <(b) (6)>, "Elliott Levy" <(b) (6)>, "Sandeep Menon" <(b) (6)>, "Amanda Peppercorn" <(b) (6)>, "Proschan, Michael (NIH/NIAID) [E]" <(b) (6)>, "Read, Sarah (NIH/NIAID) [E]" <(b) (6)>, "Amanda Peppercorn" <(b) (6)>, "Price, Dionne (FDA/CDER)" <(b) (6)>, "Rubin, Daniel B. (FDA/CDER)" <(b) (6)>, "Shen, Yuan Li (FDA/CDER)" <(b) (6)>, "Farley, John" <(b) (6)>

(FDA/CDER)" (b) (6) "Goff, David (NIH/NHLBI) [E]" (b) (6) >, "Vincent, Michael"  
(b) (6)  
Cc: "Mary Biggs" < (b) (6) "Demarcus" (b) (6) , "Macone, Erin"  
(b) (6) >, "Tountas, Karen (FNIH) [T]" (b) (6) "Wachtel, Jonathan"  
(b) (6) , "Elizabeth Kim" (b) (6) , "Parker, Ashley (NIH/OD) [E]"  
< (b) (6) "Butcher, Tina" < (b) (6) "Wholley, David (FNIH) [T]"  
(b) (6) , "Melencio, Cheryl (FNIH) [T]" (b) (6) >, "Wung, Peter /US"  
(b) (6) , "Qashu, Felicia (NIH/OD) [E]" (b) (6) "Stratton, Benjamin"  
(b) (6)

**Subject:** RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the materials for tomorrow's meeting.

1. Agenda
2. Slides for discussion updated with the decisions from today
3. A useful resource about current standard clinical treatment guidelines from the front lines for COVID. This may be a useful resource in selecting how to do minimal data collection and trying to understand SOC.

Please let me know if you have questions or other things you think would be helpful for the group to review.

Thanks,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnerships  
Direct: (b) (6) | Mobile: (b) (6)

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**From:** Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]  
**Sent:** 7/3/2020 3:46:25 PM  
**To:** Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]  
**CC:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]  
**Subject:** RE: Gallo and OPV  
**Attachments:** OPV

Hi Tony, Cliff, Doug, and John (and looping in David)

Bob Gallo is back with a complaint that no one has followed up on the OPV idea. See attached. Was this discussed in the ACTIV Vaccines WG or in any other venue?

Tx, Francis

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**From:** Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>  
**Sent:** Sunday, May 3, 2020 1:45 PM  
**To:** Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Cc:** Lowy, Douglas (NIH/NCI) [E] <(b) (6)> Mascola, John (NIH/VRC) [E] <(b) (6)>  
**Subject:** RE: Gallo and OPV

Totally agree with Cliff's advice.

Anthony S. Fauci, MD  
Director  
National Institute of Allergy and Infectious Diseases  
Building 31, Room 7A-03  
31 Center Drive, MSC 2520  
National Institutes of Health  
Bethesda, MD 20892-2520  
Phone: (b) (6)  
FAX: (301) (b) (6)  
E-mail: (b) (6)

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**From:** Lane, Cliff (NIH/NIAID) [E] <(b) (6)>  
**Sent:** Sunday, May 3, 2020 1:22 PM  
**To:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Cc:** Lowy, Douglas (NIH/NCI) [E] <(b) (6)>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>



Mascola, John (NIH/VRC) [E] (b) (6)

**Subject:** Re: Gallo and OPV

Francis,

I am not sure you need any sort of detailed response. I would just send a thank-you and indicate you will be sure those working on this at NIH are aware.

Cliff

On May 3, 2020, at 12:55 PM, Collins, Francis (NIH/OD) [E] (b) (6) (wrote:

Hi all,

I'm a bit at a loss to know how to respond to Bob Gallo. The aggressive manner in which he is promoting OPV causes me to worry he has lost objectivity about its promise. But is there any chance he has something here that could work?

Francis

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**From:** Gallo, Robert (b) (6)

**Sent:** Sunday, May 3, 2020 12:07 PM

**To:** Collins, Francis (NIH/OD) [E] (b) (6)

**Subject:** RE: Your query to Dr. Kadlec

Dear Francis,

It was a pleasure to hear from you, and yes, it has been a long time since we met or even spoke. Moons ago I was set to write to you after reading your wonderful book, but I ended up instead speaking with others about it. I should add at this point that I did not quickly respond to your email of a few days ago because I simply missed it.

It is true that I strongly suggest that OPV be quickly (already it is not quickly) brought forward for induction of a strong innate immune response to prevent or markedly reduce SARS-CoV-2 infection and/or severity until the field obtains a proven safe and efficacious vaccine producing a long lasting, adaptive immunity. OPV is very safe (notably for OPV 1 and 3 as bOPV which we will use and completely safe in a vaccinated population), simple, cheap, rather obvious, yet unique among the massive number of vaccines many (maybe most) of which are the same or at least if not exactly the same aiming at the same mechanism (targeting the spike and searching for the putative correlate of neutralizing Abs.).

OPV should work for a few months and possibly longer. Also it should be working multiple times so I think could cover more than a few months, giving us time for a proven vaccine of adaptive immunity, which might be very long lasting as is hoped.

In the main the WHO comments are correct. Of course we sought and have letters of support from them as well as from many others. Though they are again supportive in their notes to you, there is one item that surprises me. They add that there was no clinical efficacy results

as yet. They know or certainly should know that there is plenty of clinical data for this concept with BCG, OPV, and live Measles vaccine. Needless to say this is what turned me on during our regular Global Virus Network (GVN) conference calls. (Incidentally GVN is an organization I have thought of bringing to your attention. I think you would find it impressive and useful). I would be happy to share with you the clinical observations with OPV if you wish.

I would like to take a small diversion, but I suspect you are aware of these things. My colleagues and I respect the WHO because of its representation and because we have colleagues/friends there as well. However, sometimes bureaucracy of a massive degree leads to inaction or even much worse-- political expediency. I won't bother you with details of these unless you ask, but I had such experiences with HTLV-1 which we discovered in 1980 as the 1<sup>st</sup> human retrovirus and which cause not only the highest incidence of cancer (% of infections) of any virus and other fatal diseases as well but mainly in less developed countries (plus Japan) and again with HIV in 1984. Behavior was not beneficial. Perhaps it will be of relevance in the future because a few at WHO took a position to remove OPV (Sabin) in favor of IPV (Salk) in their polio eradication scheme. It was a huge failure. As my FDA collaborator, Konstantin Chumakov, says "Blessed be Bill Gates" because he saved OPV and saved the day and in so doing has produced a still better OPV.

There is indeed data also for BCG as well as live Measles though I know less of the latter. BCG is less available, requires injection, harder to make, not as safe, and we think unlikely to be as effective as OPV. Nonetheless, we favor its use too. The mechanisms will be similar.

You asked whether monkey trials are planned. For several reasons definitely not --though we are planning some monkey experiments, but not large enough for "clinical" conclusions. The main reasons are: 1) cost; 2) that billions not thousands or millions have received OPV safely and in our collective view (and we know the studies pretty well) protection has been clinically shown; 3) In a pandemic we wished to move quickly (so far we must say that has not been achieved). A typical monkey vaccine study will take time, but 4) in this case it would be a huge amount of lost time as monkeys require great doses of polio for infection and monkeys have to be trained to drink their orange juice. It would be hard to imagine that such studies would even give us useful information.

On a final digression Francis I have had 36 years of on/off experiences with glycosylated spike proteins--their analyses immunologically and especially regarding use in vaccines and developing neutralizing Abs. I believe it will be a mistake to put most eggs in that basket. The risks: shortened antibody half life; 2) protection NOT correlating with neutralizing Abs; 3) sometimes hazards from them. Admittedly, they might work, but I trust and hope that not everything is going in this bag. If you wish to discuss this again I will be available.

Finally, I had no idea you were into vaccines or SARS-2 nor any part of CoVID-19 disease, but I am very happy to learn this.

Thanks.

Bob Gallo

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**From:** Collins, Francis (NIH/OD) [E] (b) (6)

**Sent:** Thursday, April 30, 2020 5:00 PM

COLL0000020886-2516973



**To:** Gallo, Robert <(b) (6)>  
**Cc:** Disbrow, Gary (OS/ASPR/BARDA) (b) (6); Kadlec, Robert (OS/ASPR/IO) (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Shuy, Bryan (OS/ASPR/IO) <(b) (6)>; Johnson, Robert (OS/ASPR/BARDA) (b) (6); Mascola, John (NIH/VRC) [E] (b) (6); Lane, Cliff (NIH/NIAID) [E] (b) (6)  
**Subject:** Your query to Dr. Kadlec

**CAUTION:** This message originated from a non UMB, UMSOM, FPI, or UMMS email system. Whether the sender is known or not known, hover over any links before clicking and use caution opening attachments.

Dear Bob,

It's been quite a while since we've chatted. Bob Kadlec asked me to respond to your query about the possible use of OPV to activate innate immunity and provide COVID-19 protection. Has this been tested in a non-human primate model? I note the recommendation below that says a clinical trial is planned – can you tell me more about that?

As you can imagine, we are all flat out on the vaccine development pathway!

Francis

### **The use of oral polio vaccine (OPV) to prevent SARS-CoV2 (Polio Eradication Campaign)**

There is no evidence that oral poliovirus vaccine (OPV) protects people against infection with COVID-19 virus.

A clinical trial addressing this question is planned in the USA, and WHO will evaluate the evidence when it is available.

In the absence of evidence, WHO does not recommend OPV vaccination for the prevention of COVID-19. WHO continues to recommend OPV as part of essential immunization services to prevent poliomyelitis and as part of global polio eradication efforts.

There are experimental signals from various studies over the years that OPV has non-specific effects on the immune system. These effects have not been well characterized and their clinical relevance is unknown. Such non-specific effects may not be limited to OPV, as other live vaccines have also been associated with non-specific protective effects (such as BCG vaccine against tuberculosis). Nonlive vaccines in contrast do not seem to have the same effects.

The exact mechanism of non-specific protection induced by live vaccines needs to be elucidated further. Clinical studies could begin immediately because the vaccines in question are licensed and have an excellent safety record. Clinical trials involving off-label use of various drugs licensed for other indications are currently underway. The existing scientific rationale suggests that the same should be done for OPV and other live vaccines. A study is currently being discussed with various partners and vaccine manufacturers, including the US FDA, the outcomes of which will be carefully assessed to determine potential use in the context of the spread of SARS-CoV2 until the time when specific vaccines and antiviral therapies are ready.



---

**From:** Kadlec, Robert (OS/ASPR/IO) (b) (6) >  
**Sent:** Thursday, April 30, 2020 10:28 AM  
**To:** Gallo, Robert (b) (6) >; Collins, Francis (NIH/OD) [E] (b) (6)  
Tabak, Lawrence (NIH/OD) [E] (b) (6) >; Shuy, Bryan (OS/ASPR/IO)  
(b) (6)  
**Subject:** Re: Response

Dr Gallo thank you for your note and I appreciate you reaching out to me. I have copied Dr Collins and Dr Tabak to consider the ACTIV forum they have created to bring industry academia and government to consider scientific base approaches That you have described. Dr Collins has organized a vaccine group and I assess could be the best and fastest place to discuss your concept. I am sure they will connect with you soonest

Best

Bob Kadlec.

Sent from my iPhone

On Apr 30, 2020, at 10:02 AM, Gallo, Robert (b) (6) > wrote:

Dear Dr. Kadlec,

I have not heard from you in over a week. You mentioned getting back to me in a day or two. Time is passing. I am asking you to look at OPV 1 plus 3 serotypes as a bivalent, completely safe vaccine with powerful stimulation of innate immunity lasting several weeks , which can be given a second or third time, and with a historical track record of preventing other infections from entirely different RNA viruses (such as protecting against influenza). Therefore, it should be really helpful for some months, and I think get us past a second wave of SARS-CoV-2, and help people return to work safely. I don't understand delays or apparent lack of interest. Who can possibly be against this? If you hear of hypothetical problems we can show you that these are false. Just ask the questions, and we can give you the evidence.

However, no answer from you suggests no interest and must quickly make alternative pathways. I am though quite surprised and fear you are receiving "fake news" if you will pardon the expression. Some have been against this who defend their old and failed position on polio eradication with their promotion of the use of the inactivated polio virus vaccine. Please note that in the US between 1962 and 1985 we received (safely) the oral polio (OPV). Moreover, if vaccinated already there has not been a single case of a complication and BILLIONS have received it. No it will not last long as innate immunity is short lived, but we strongly believe that we can break the back of the SARS-CoV-2 spread. Also note that this is what Bill Gates is doing now in India and much of the Eastern hemisphere.

There are countries outside the US wanting to move fast on this. We are waiting for your reply.

Robert Gallo  
Director, Institute of Human Virology,  
Professor of Medicine and Professor of Microbiology,  
UMB, School of Medicine, Baltimore,

And  
Co-founder and International Science Advisor of the Global Virus Network (GVN)

**From:** Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]  
**Sent:** 7/21/2020 7:19:34 PM  
**To:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] (b) (6); Bancel, Stephane [ (b) (6) Carter, Kara [ (b) (6) Cavaleri, Marco [ (b) (6) Cihlar, Tomas [ (b) (6) Collins, Francis (NIH/OD) [E] [coll (b) (6)]; Corey, Larry [ (b) (6) Culp, Michelle (NIH/OD) [E] (b) (6) Disbrow, Gary (OS/ASPR/BARDA) [ (b) (6) Dolsten, Mikael [ (b) (6) Erbeling, Emily (NIH/NIAID) [E] [ (b) (6) Erck, Stan [ (b) (6) Fauci, Anthony (NIH/NIAID) [E] [ (b) (6) Gadbois, Ellen (NIH/OD) [E] [ (b) (6) Gibbons, Gary (NIH/NHLBI) [E] [ga (b) (6) Hudson, Thomas [ (b) (6) James, Stephanie (FNIH) [T] [ (b) (6) Johnson, Robert (OS/ASPR/BARDA) [ (b) (6)]; Kramer, Lynn [ (b) (6) Lane, Cliff (NIH/NIAID) [E] [ (b) (6) Lepore, John [ (b) (6) Marks, Peter (FDA/CBER) [ (b) (6)]; Marston, Hilary (NIH/NIAID) [E] [hila (b) (6) Mascola, John (NIH/VRC) [E] (b) (6)]; Meeker, David [ (b) (6) Menetski, Joseph (FNIH) [T] [ (b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) [ (b) (6) Pandya, Hitesh [ (b) (6) Pao, William [ (b) (6) Parker, Ashley (NIH/OD) [E] [ (b) (6) Perlmutter, Roger [ (b) (6) Plenge, Robert [ (b) (6) Plump, Andy [ (b) (6) Rachel Ramoni [rachel. (b) (6) Rasi, Guido [ (b) (6)]; Reed, John [ (b) (6) Reese, David [ (b) (6)]; Rouse, Doris [ (b) (6) Santos, Michael (FNIH) [T] [ (b) (6) Skovronsky, Daniel [ (b) (6) Stein, Peter (FDA/CDER) [ (b) (6)]; Stoffels, Paul [ (b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael [ (b) (6) Tsai, John [ (b) (6) Vessey, Rupert [ (b) (6)]; Virgin, Skip [ (b) (6); Wholley, David (FNIH) [T] [dwhol (b) (6) Woodcock, Janet (FDA/CDER) [ (b) (6) Young, John [ (b) (6) Colvis, Christine (NIH/NCATS) [E] [christine.colvis@nih.gov]; Desrosiers, Betsy [el (b) (6) Eric Hughes [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [ (b) (6) Lowy, Douglas (NCI) [ (b) (6); Read, Sarah (NIH/NIAID) [E] [ (b) (6) Villafana, Tonya [ (b) (6) Brian Rosen [ (b) (6) Pangalos, Mene [ (b) (6) Paul, Steve [ (b) (6) Adam, Stacey (FNIH) [T] [ (b) (6) Alvarez, Rosa [ (b) (6) Anderson, Margaret [ (b) (6) Chen, Helen [ (b) (6) Elsaid, Olivia [ (b) (6) Gonzalez, Nina [ (b) (6) Stratton, Benjamin [ (b) (6) Tolman, Brett [ (b) (6) Tountas, Karen (FNIH) [T] [ktount (b) (6) Wachtel, Jonathan [ (b) (6)]; Anderson, James (NIH/OD) [E] [ (b) (6) Burklow, John (NIH/OD) [E] [ (b) (6) .gov]; Castillejos, Carlos [ (b) (6) .com]; FNIH Central Account [ (b) (6) Hallett, Adrienne (NIH/OD) [E] [ (b) (6) Myles, Renate (NIH/OD) [E] (b) (6)]; Wolinetz, Carrie (NIH/OD) [E] [ (b) (6)]; Burrus-Shaw, Cyndi (NIH/OD) [E] (b) (6) Carver, Treia (NIH) [C] [treia. (b) (6) Hardesty, Rebecca (NIH/OD) [E] [ (b) (6) Lagos, Enrique (NIH/NCATS) [E] (b) (6); Sepulveda, Dorina (FNIH) [T] [ (b) (6) Simon, Dina (NIH/OD) [C] [d (b) (6) Gorman, Greta (FNIH) [T] [ (b) (6) Meltzer, Abbey (FNIH) [T] [ (b) (6) Togashi, Mieko (NIH/NCI) [E] [ (b) (6) Underwood, Nancy [ (b) (6) Zottoli, Jessica [Jessica.Zottol (b) (6) Austin, Sarah (NIH/NIAID) [E] [austinsj@niaid.nih.gov]; Barasch, Kimberly (NIH/NIAID) [C] [ (b) (6) Conrad, Patricia (NIH/NIAID) [E] [conradpa@niaid.nih.gov]; Dimishkov, Roxanne (NIH/NHLBI) [C] [ (b) (6) Edl, Susan [ (b) (6) Giorgi, Sara [sara. (b) (6) Hoban, Michelle [ (b) (6) Hoffstetter, Renata (FNIH) [T] [ (b) (6) Iberdemaj, Vaide [va (b) (6) Lever, Susan [ (b) (6) McManus, Ayanna (NIH/OD) [E] [ (b) (6)]; Minnich, Beth [ (b) (6) Perala, Mie [ (b) (6) Protasiewicz, Ann [ (b) (6) Riccobene, Kim [ (b) (6) Riffin, Mary [ (b) (6) Ripley, Nadege [ (b) (6) Suhana, Tina (NIH/VRC) [E] [ (b) (6) Thomas, Ashley (FDA/CDER) [ (b) (6) Wood, Gretchen (NIH/OD) [E] [ (b) (6) David



Meeker [ (b) (6) Dana Carluccio [ (b) (6) Hawk, Harrison  
[ (b) (6) Lucas Smalldon [ (b) (6) Hamilton, Nancy  
[ (b) (6) Lowy, Douglas (NIH/NCI) [E] [ (b) (6) ]; Vessey, Rupert  
[ (b) (6) ]

**Subject:** ACTIV Leadership Team Call #7

**Location:** <https://fnih.zoom.> (b) (6)

**Start:** 8/26/2020 7:00:00 PM

**End:** 8/26/2020 8:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Villafana, Tonya; Brian Rosen

**Optional Attendees:** Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hardesty, Rebecca (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Lever, Susan; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggan, Mary; Ripley, Nadege; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; David Meeker; Dana Carluccio; Hawk, Harrison; Vessey, Rupert; Lucas Smalldon; Hamilton, Nancy; Lowy, Douglas (NIH/NCI) [E]

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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 4/19/2020 8:39:51 PM  
**To:** Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan\_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [ (b) (6) ]; Eisner, Mark [ (b) (6) ]; Gottesdiener, Keith [ (b) (6) ]; Hughes, Eric [ (b) (6) ]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [ (b) (6) ]; LaVange, Lisa [ (b) (6) ]; Levy, Elliot [ (b) (6) ]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [ (b) (6) ]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [ (b) (6) ]; Peppercorn, Amanda [ (b) (6) ]; Poole, Mike [ (b) (6) ]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Amanda Peppercorn [ (b) (6) ]  
**CC:** Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]  
**Subject:** Time Sensitive Request for Response from ACTIV Therapeutics-Clinical Working Group

Dear ACTIV Therapeutics-Clinical Working Group Members,

I hope this message finds you well. I am writing to seek your approval to publicly list your name in association with this ACTIV working group. A reporter has reached out to the FNIH asking for the names of the working group members, and we would like to point them to a listing of these names on the FNIH website, once you have provided clearance for this.

The FNIH's Vice President of Communications and Events, Abbey Meltzer, will be tracking these approvals, so please send your approval to her at (b) (6). If you have any questions, please do not hesitate to reach out to Abbey.

Best,  
Stacey

Stacey J. Adam, PhD

APAR0000023373-2516975



Director, Cancer

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---

**From:** Allen-Gifford, Patrice (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=67262490D6D441B48EFEC1AFF0700250-ALLEGIFFOR]  
**Sent:** 8/26/2020 11:27:57 AM  
**To:** Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]  
**Subject:** RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Thanks Ashley. I have it ready to go and had made the same adjustments. One question: rather than conference call, should it reference the COVID-19 call so ICDs who didn't participate in that won't think they missed an ICD meeting?

---

**From:** Parker, Ashley (NIH/OD) [E] <(b) (6)>  
**Sent:** Wednesday, August 26, 2020 7:25 AM  
**To:** Collins, Francis (NIH/OD) [E] <(b) (6)> Allen-Gifford, Patrice (NIH/OD) [E] <(b) (6)>  
(b) (6)  
**Cc:** Wholley, David (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)> Gladman, Jordan (NIH/OD) [E] <(b) (6)>  
**Subject:** RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Thank you, Francis.

Good morning Patrice,

I've made a few adjustments to the email below to go out to the ICD ONLY list this morning and reattached the materials.

Thanks,  
Ashley

**To:** [ICD-ONLY-L@LIST.NIH.GOV](mailto:ICD-ONLY-L@LIST.NIH.GOV)  
**Cc:** Wholley, David (FNIH) [T] <(b) (6)>; Melencio, Cheryl (FNIH) [T] <(b) (6)>  
**Bcc:** Parker, Ashley (NIH/OD) [E] <(b) (6)>

Dear Colleagues,

As discussed during our conference call yesterday, ICDs (**principals only please; no surrogates or additional staff**) are invited to join the virtual ACTIV leadership team meeting **today August 26, 3:00-4:00pm**. Please see the attached materials and link below. If you are able to join please ensure David Wholley and Cheryl Melencio know you are available to attend and please remain in "listen-only" mode during the meeting.

Thank you,  
Francis

---

**From:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Sent:** Wednesday, August 26, 2020 5:57 AM  
**To:** Parker, Ashley (NIH/OD) [E] <(b) (6)>  
**Cc:** Wholley, David (FNIH) [T] <(b) (6)>; Melencio, Cheryl (FNIH) [T] <(b) (6)> Gladman, Jordan (NIH/OD) [E] <(b) (6)> Allen-Gifford, Patrice (NIH/OD) [E] <(b) (6)>  
**Subject:** RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Be sure to change the text of the e-mail from "tomorrow" to "today".

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Wednesday, August 26, 2020 5:56 AM  
**To:** Parker, Ashley (NIH/OD) [E] (b) (6)  
**Cc:** Wholley, David (FNIH) [T] (b) (6); Melencio, Cheryl (FNIH) [T] (b) (6); Gladman, Jordan (NIH/OD) [E] (b) (6); Allen-Gifford, Patrice (NIH/OD) [E] (b) (6)  
**Subject:** RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Yes, this note would be great. Looping in Exec Sec to ask that it be sent first thing this morning.

Francis

---

**From:** Parker, Ashley (NIH/OD) [E] <(b) (6)>  
**Sent:** Tuesday, August 25, 2020 10:52 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Wholley, David (FNIH) [T] (b) (6); Melencio, Cheryl (FNIH) [T] (b) (6); Gladman, Jordan (NIH/OD) [E] <(b) (6)>  
**Subject:** Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference  
**Importance:** High

Hi Francis,

To ensure the ICDs receive the information for the ACTIV LT meeting tomorrow – would you like to forward the following to the ICD only list. Below is a draft note for consideration.

**To:** [ICD-ONLY-L@LIST.NIH.GOV](mailto:ICD-ONLY-L@LIST.NIH.GOV)  
**Cc:** Wholley, David (FNIH) [T] (b) (6); Melencio, Cheryl (FNIH) [T] (b) (6)

Dear Colleagues,

As discussed during our conference call this afternoon, ICDs (**principals only please; no surrogates or additional staff**) are invited to join the virtual ACTIV leadership team meeting tomorrow August 26, 3:00-4:00pm. Please see the attached materials and link below. If you are able to join please ensure David Wholley and Cheryl Melencio know you are available to attend and please remain in “listen-only” mode during the meeting.

Thank you,  
Francis

---

**From:** Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]  
**Sent:** Tuesday, August 25, 2020 9:47 PM  
**To:** Austin, Christopher (NIH/NCATS) [E] <(b) (6)>; Bancel, Stephane  
<(b) (6)>; Carter, Kara (b) (6); Cavaleri, Marco  
(b) (6); Cihlar, Tomas (b) (6); Collins, Francis (NIH/OD) [E]  
(b) (6); Corey, Larry (b) (6); Culp, Michelle (NIH/OD) [E] (b) (6);  
Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)>; Dolsten, Mikael (b) (6); Erbelding,  
Emily (NIH/NIAID) [E] <(b) (6)>; Erck, Stan (b) (6); Fauci, Anthony (NIH/NIAID) [E]  
(b) (6); Freire, Maria (FNIH) [T] (b) (6); Gadbois, Ellen (NIH/OD) [E]  
(b) (6); Gibbons, Gary (NIH/NHLBI) [E] (b) (6); Hudson, Thomas  
<(b) (6)>; James, Stephanie (FNIH) [T] <(b) (6)>; Johnson, Robert (OS/ASPR/BARDA)  
(b) (6); Kramer, Lynn (b) (6); Lane, Cliff (NIH/NIAID) [E] <(b) (6)>  
Lepore, John <(b) (6)>; Marks, Peter (FDA/CBER) (b) (6); Marston, Hilary



(NIH/NIAID) [E] < (b) (6) Mascola, John (NIH/VRC) [E] < (b) (6) Meeker, David  
 (b) (6) ; Menetski, Joseph (FNIH) [T] (b) (6) ; Messonnier, Nancy  
 (CDC/DDID/NCIRD/OD) (b) (6) ; Pandya, Hitesh (b) (6) ; Pangalos, Mene  
 < (b) (6) ; Pao, William (b) (6) ; Parker, Ashley (NIH/OD) [E]  
 < (b) (6) Paul, Steve (b) (6) >; Perlmutter, Roger (b) (6) ;  
 Plenge, Robert < (b) (6) Plump, Andy (b) (6) ; Rachel Ramoni  
 (b) (6) ; Rasi, Guido < (b) (6) >; Reed, John (b) (6) >; Reese, David  
 (b) (6) ; Rouse, Doris < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) ; Skovronsky,  
 Daniel (b) (6) >; Stein, Peter (FDA/CDER) (b) (6) ; Stoffels, Paul  
 (b) (6) ; Tabak, Lawrence (NIH/OD) [E] (b) (6) ; Talley, Michael  
 (b) (6) ; Tsai, John (b) (6) >; Vessey, Rupert < (b) (6) ; Virgin, Skip  
 (b) (6) Wholley, David (FNIH) [T] < (b) (6) ; Woodcock, Janet (FDA/CDER)  
 (b) (6) ; Young, John (b) (6) ; Colvis, Christine (NIH/NCATS) [E]  
 (b) (6) ; Desrosiers, Betsy < (b) (6) ; Eric Hughes  
 (b) (6) ; Jansen, Kathrin (b) (6) ; Kurilla, Michael (NIH/NCATS) [E]  
 (b) (6) Lowy, Douglas (NCI) < (b) (6) Read, Sarah (NIH/NIAID) [E] (b) (6)  
 Young, John (b) (6) >  
**Cc:** Adam, Stacey (FNIH) [T] < (b) (6) ; Alvarez, Rosa < (b) (6) ; Anderson, Margaret  
 (b) (6) ; Chen, Helen (b) (6) ; Elsaid, Olivia (b) (6) >;  
 Gonzalez, Nina (b) (6) ; Hawk, Harrison (b) (6) >; Menetski, Joseph (FNIH) [T]  
 (b) (6) ; Santos, Michael (FNIH) [T] < (b) (6) ; Stratton, Benjamin < (b) (6)  
 btolman (b) (6) >; Tountas, Karen (FNIH) [T] (b) (6) ; Wachtel, Jonathan  
 (b) (6) ; Wholley, David (FNIH) [T] (b) (6) ; Anderson, James (NIH/OD) [E]  
 (b) (6) >; Austin, Christopher (NIH/NCATS) [E] (b) (6) ; Burklow, John (NIH/OD) [E]  
 < (b) (6) ; Castillejos, Carlos (b) (6) ; Culp, Michelle (NIH/OD) [E]  
 (b) (6) ; FNIH Central Account < (b) (6) ; Freire, Maria (FNIH) [T]  
 (b) (6) ; Gadbois, Ellen (NIH/OD) [E] (b) (6) ; Hallett, Adrienne (NIH/OD) [E]  
 (b) (6) ; Lane, Cliff (NIH/NIAID) [E] (b) (6) ; Myles, Renate (NIH/OD) [E]  
 < (b) (6) ; Parker, Ashley (NIH/OD) [E] < (b) (6) ; Tabak, Lawrence (NIH/OD) [E]  
 (b) (6) ; Wolinetz, Carrie (NIH/OD) [E] (b) (6) ; Burklow, John (NIH/OD) [E]  
 (b) (6) >; Gorman, Greta (FNIH) [T] < (b) (6) ; Hallett, Adrienne (NIH/OD) [E]  
 < (b) (6) ; Meltzer, Abbey (FNIH) [T] (b) (6) ; Myles, Renate (NIH/OD) [E]  
 (b) (6) ; Wolinetz, Carrie (NIH/OD) [E] < (b) (6) ; Lucas Smalldon  
 (b) (6) ; Villafana, Tonya < (b) (6) >; Brian Rosen  
 < (b) (6)

**Subject:** Materials for August 26 ACTIV Partnership Leadership Team Teleconference

**Importance:** High

Dear Colleagues:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 3:00 – 4:00 PM Eastern U.S. time tomorrow, Wednesday August 26. (As a reminder, this meeting and future LT meetings are 60 minutes in length.) I have also attached notes from our July 29 Leadership Team meeting as well as our last ACTIV EC meeting on August 14.

The Zoom meeting information is:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley  
Senior Vice-President, Research Partnerships  
Foundation for the National Institutes of Health

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**From:** Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]  
**Sent:** 7/10/2020 5:58:52 PM  
**To:** Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]  
**Subject:** RE: ACTIV Clinical Trial Capacity survey dashboard

Hi Michelle,

You're probably not spending a lot of time using the ACTIV dashboard, but I was wondering whether you have taken a look lately and what you think? Have you heard comments from anyone – positive is always welcome, and constructive criticism will help improve the user experience.

Many thanks!  
Karen

---

**From:** Culp, Michelle (NIH/OD) [E] <(b) (6)>  
**Sent:** Friday, May 22, 2020 11:38 AM  
**To:** Wachtel, Jonathan <(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)>  
**Cc:** Tountas, Karen (FNIH) [T] <(b) (6)>  
**Subject:** RE: ACTIV Clinical Trial Capacity survey dashboard

Thanks. I got in!

---

**From:** Wachtel, Jonathan <(b) (6)>  
**Sent:** Friday, May 22, 2020 10:28 AM  
**To:** Culp, Michelle (NIH/OD) [E] <(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)>  
**Cc:** Tountas, Karen (FNIH) [T] <(b) (6)>  
**Subject:** FW: ACTIV Clinical Trial Capacity survey dashboard  
**Importance:** High

Michelle/Ellen

Access granted. Please find the link below.

Best,

**Jonathan Wachtel**  
Deloitte Consulting LLP  
Tel/Direct: (b) (6)  
[www.deloitte.com](http://www.deloitte.com)

---

**From:** Tountas, Karen (FNIH) [T] <(b) (6)>  
**Sent:** Wednesday, May 20, 2020 4:13 PM  
**To:** Bascles, Lionel <(b) (6)>; Cohen, Myron <(b) (6)>; Corey, Larry <(b) (6)> Victoria Davey <(b) (6)> Desrosiers, Betsy <(b) (6)> Dickens, Jim (NIH/NCATS) [C] <(b) (6)>; Doroshow, James (NIH/NCI) [E] <(b) (6)>; Garner, Carlos <(b) (6)> Goff, David (NIH/NHLBI) [E] <(b) (6)> Kurilla, Michael (NIH/NCATS) [E] <(b) (6)> Mensah, George (NIH/NHLBI) [E] <(b) (6)> Nayak, Seema (NIH/NIAID) [E] <(b) (6)> Payton, Manizhe (NIH/NIAID) [E] <(b) (6)>; Resnansky, Laura <(b) (6)>; Sizemore, Christine (NIH/FIC) [E]

(b) (6) >; Srinivasan, Badhri (b) (6) >; Stein, Peter (FDA/CDER)  
(b) (6) /incent, Mike (b) (6) ; Weinmann, Gail (NIH/NHLBI) [E]  
< (b) (6)  
Cc: Wachtel, Jonathan (b) (6) Footer, Kevin (b) (6) Jones, Ethan  
(b) (6) ; Long, Alyssa (b) (6)  
**Subject:** [EXT] ACTIV Clinical Trial Capacity survey dashboard  
**Importance:** High

Dear Colleagues,

BLUF\*: The ACTIV Clinical Trial Capacity survey dashboard is ready for use  
Caveat – Now for those with NIH credential, and in a few days for those external to the NIH system

After several unforeseen technical issues with both the data and the infrastructure, the clinical network and site the dashboard is ready for use. A big thank you to Jonathan and Kevin and the team at Deloitte for putting this dashboard together. We're not letting them off the hook that easily – they already are working on incorporating the CRO-SMO survey data.

For those of you with NIH credentials, you will be able to access the dashboard through this link:  
<https://analyticsqa.niaid.nih.gov/#/site/ACTIV/views/ACTIVCTCWGSurveyDashboard/Network-SiteMap?iid=1>. You will find four tabs at the top of the page: 1) Network-Site Map, a dashboard with the map (sites and COVID-19 data, by USA with county-level data or world-wide, country-level views) and the network and site filters; 2) Network Detail Dashboard, a one-page summary of the network based on the survey responses; 3) Glossary, a few definitions that we have been using; and, 4) Resources that might be of interest. I have poked around the dashboard a bit – use is fairly intuitive, but if you have questions please feel free to reach out to Kevin, Ethan, or Alyssa (copied on this email). However, please note that the dashboard is “hot off the press” so if you notice any issues with the dashboard, or would like to pass along thoughts that might improve the user experience, please bring them to the attention of Kevin, Ethan, or Alyssa.

The team is working on getting everyone else on the WG access, targeting the end of this week. Apparently, this has proved a bit more challenging for the NIH group that hosts this platform than anticipated.

As you all know,  
Karen

**Karen H. Tountas, PhD**  
Scientific Program Manager  
**Foundation for the National Institutes of Health**  
(b) (6) | [fnih.org](https://fnih.org)  
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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\*BLUF = bottom line up front

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**From:** Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]  
**Sent:** 5/12/2020 4:49:13 PM  
**To:** Woodcock, Janet [ (b) (6) ]  
**Subject:** RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group  
  
**Flag:** Follow up

Yes, I would like that. Can you do 3:30?

---

**From:** Woodcock, Janet < (b) (6) >  
**Sent:** Tuesday, May 12, 2020 11:28 AM  
**To:** Collins, Francis (NIH/OD) [E] < (b) (6) >  
**Subject:** FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Can we discuss before tomorrow? jw

---

**From:** Wholley, David (FNIH) [T] (b) (6)  
**Sent:** Tuesday, May 12, 2020 10:46 AM  
**To:** Collins, Francis S (NIH) (b) (6); Stoffels, Paul [JJCUS] (b) (6); Fauci, Anthony S (NIH) (b) (6); Gibbons, Gary H (NIH) (b) (6); Woodcock, Janet < (b) (6) >; Pao, William (b) (6); Dolsten, Mikael < (b) (6) >  
**Cc:** Colvis, Christine M (NIH) < (b) (6) >; Desrosiers, Betsy (b) (6); Hughes, Eric < (b) (6) >; Read, Sarah W (NIH) (b) (6); Jansen, Kathrin (b) (6); Kurilla, Michael G (NIH) < (b) (6) >; Lowy, Douglas R (NIH) (b) (6); Young, John (b) (6); Freire, Maria C (NIH) (b) (6); Tabak, Lawrence A (NIH) (b) (6); Lane, Henry C (NIH) (b) (6); Parker, Ashley S (NIH) (b) (6); Anderson, James M (NIH) (b) (6); Austin, Christopher P (NIH) (b) (6); Wolinetz, Carrie D (NIH) < (b) (6) >  
**Subject:** FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Dear ACTIV Executive Committee Members:

Please see the attached letter from the ACTIV Therapeutics-Clinical Working Group received this morning, for consideration on tomorrow morning's Executive Committee teleconference. While we expect the proposals contained herein will be one major topic of discussion, the purpose of the meeting is to hear from all of the Working Group co-chairs (copied on this note) regarding what is working and where they may be facing challenges in ACTIV, and jointly discuss strategy moving forward.

David

---

**From:** Adam, Stacey (FNIH) [T] (b) (6)  
**Sent:** Tuesday, May 12, 2020 9:52 AM  
**To:** Wholley, David (FNIH) [T] < (b) (6) >  
**Cc:** Read, Sarah (NIH/NIAID) [E] (b) (6); Eric Hughes (b) (6); Carlos O Garner (b) (6); Judy Currier (b) (6); Keith Gottesdiener (b) (6); Amanda Peppercorn < (b) (6) >; Stein, Peter (FDA/CDER) (b) (6); Higgs, Elizabeth (NIH/NIAID) [E] (b) (6)  
**Subject:** Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Hi David,

Please find attached a letter from the Therapeutics-Clinical Working Group to the ACTIV Executive Committee for their consideration. Overall, the letter is meant to relate some broad challenges and issues that the Therapeutics-Clinical group thinks the ACTIV PPP is facing, as well as some very specific requests for assistance from the ACTIV EC for our team.

Please relay this to the ACTIV EC for their review. Our group would welcome any feedback they have.

Thanks,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnerships  
Foundation for the National Institutes of Health  
Direct: (b) (6) | Mobile: (b) (6)  
[fnih.org](http://fnih.org)  
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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**From:** Menetski, Joseph (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]  
**Sent:** 4/14/2020 5:23:50 PM  
**To:** (b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];  
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];  
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];  
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]  
**CC:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Hughes, Eric [ (b) (6) Jansen, Kathrin  
(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [ (b) (6) Kim, Elizabeth [ (b) (6) Tolman, Brett [ (b) (6) Wachtel, Jonathan [ (b) (6) Prabhavathi Fernandes [ (b) (6) Diamond, Michael [ (b) (6) Rose Li [ (b) (6) Dana Carluccio [ (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group





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**From:** Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]  
**Sent:** 5/29/2020 10:44:43 PM  
**To:** Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]  
**Subject:** Re: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Yes, she is waiting to see the draft ppts and will advise on the strategy then.

Sent from my iPhone

On May 29, 2020, at 6:06 PM, Freire, Maria (FNIH) [T] < (b) (6) > wrote:

Francis - have you had a chance to chat with Janet to coordinate messages? She is critical - in her low-key way, she is able to carry a huge part of the load. Moncef knows she has a rock-solid reputation with industry folks. And, of course, she was the one who asked for the money. M.

On May 29, 2020, at 5:59 PM, Collins, Francis (NIH/OD) [E] < (b) (6) > wrote:

Hi all,

I have received information from Amy Patterson about the anticoagulant trial, and I'd like to have that incorporated into the slide set that Deloitte is currently working on. Attached is the document from Amy. I have highlighted the main points that I would want to have included in the slides, trying if possible to mirror the same features that are going to be included in the description of the immunomodulator study.

See what you think. I stand ready to look at ppts anytime this evening.

One question about the immunomodulator trial that I noticed in Moncef's note – has FDA agreed with the plan to move straight into phase 3 from a safety and efficacy standpoint?

Thanks, Francis

---

**From:** Wholley, David (FNIH) [T] < (b) (6) >  
**Sent:** Friday, May 29, 2020 1:59 PM  
**To:** Collins, Francis (NIH/OD) [E] < (b) (6) >  
**Cc:** Adam, Stacey (FNIH) [T] < (b) (6) > Freire, Maria (FNIH) [T] < (b) (6) > Gonzalez, Nina < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) >  
**Subject:** Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Francis:

Here is the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1; it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to



highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
- OWS/ACTIV Therapeutics has been taking a **portfolio** approach to addressing the dramatic health and economic challenges posed by the pandemic, with harmonized efforts that address both disease etiology and symptomology.
  - ACTIV Baricitinib (ACTT2, sponsored by NIAID) – in progress
  - ACTIV hiVIG (sponsored by NIAID) - in progress
  - ACTIV-1 – Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) – (Phase III) – ready to launch late June
  - ACTIV-2\*– Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) – (Phase II/III) – projected launch June
  - ACTIV-3\* – Neutralizing Monoclonal Antibodies Inpatient Master Protocol (NIAID INSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/III) – projected launch July
  - ACTIV-4 – Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually, Anticoagulant+Immune Modulator Combinations (NHLBI-NINDS “Master” Network) – (Phase II/III) – projected launch late June
  - ACTIV-5 – De Novo Master Protocol Structure to test promising agents not effectively evaluated elsewhere (e.g., antivirals) – similar design to the mAb protocols, networks/sites/agents in discussions now – projected launch August (*if needed; i.e. if agents are not incorporated into mAb protocols*)
    - \* current priority

[for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base
- Prioritization Process (v 2.0) for ACTIV : (slide 14 from May 20 EC deck)
- Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)  
[Key Criteria for Scoring (slide 15 from 5/20) can go to backup
- Prioritization and Protocol Design: Who is Involved – two-box slide containing names and affiliations of those involved in the Prioritization and MP Subgroups (quality folks!)
- ACTIV-1 Protocol for immunomodulators
  - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)
  - 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
  - All 3 either have initial Phase II data or are currently running company-sponsored Phase II trials = high POS
  - Phase III master protocol design for ACTIV-1 includes aggressive efficacy and futility assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)
  - Companies have agreed to share data + common control arm+ common endpoints + DSMB = efficiency and ability to compare results across arms (this does not happen if companies test separately)
  - Protocol is 80% complete
    - Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
      - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)

- All three companies have written their sections of the protocols, which are being merged into the master design
  - Working with OWS/BARDA on choice of CRO to run the trial; (b) (5)
- “ACTIV-4” Protocol for anticoagulants
  - Need bullets from NHBLI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS “network of networks” with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the clinical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley  
 Senior Vice-President, Research Partnerships  
 Foundation for the National Institutes of Health

(b) (6)

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<Responses to Qs re AC Clinical Trial Strategy 052920 final fsc.docx>



**From:** Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]  
**Sent:** 9/25/2020 5:00:39 PM  
**To:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] (b) (6); Carter, Kara [ (b) (6) ] Cavaleri, Marco [ (b) (6) ] Cihlar, Tomas [ (b) (6) ]; Collins, Francis (NIH/OD) [E] [ (b) (6) ] Corey, Larry [ (b) (6) ] Culp, Michelle (NIH/OD) [E] [ (b) (6) ] Disbrow, Gary (OS/ASPR/BARDA) [ (b) (6) ] Dolsten, Mikael [ (b) (6) ] Erbeling, Emily (NIH/NIAID) [E] [ (b) (6) ]; Erck, Stan [ (b) (6) ] Gadbois, Ellen (NIH/OD) [E] [ (b) (6) ] Gibbons, Gary (NIH/NHLBI) [E] [ (b) (6) ] Hudson, Thomas [ (b) (6) ] James, Stephanie (FNIH) [T] [ (b) (6) ] Johnson, Robert (OS/ASPR/BARDA) [ (b) (6) ] Kramer, Lynn [ (b) (6) ] Lane, Cliff (NIH/NIAID) [E] [ (b) (6) ] Lepore, John [ (b) (6) ]; Marks, Peter (FDA/CBER) [ (b) (6) ] Marston, Hilary (NIH/NIAID) [E] [ (b) (6) ] Mascola, John (NIH/VRC) [E] [ (b) (6) ]; Meeker, David [ (b) (6) ] Menetski, Joseph (FNIH) [T] [ (b) (6) ] Messonnier, Nancy (CDC/DDID/NCIRD/OD) [ (b) (6) ] Pandya, Hitesh [ (b) (6) ] Pao, William [ (b) (6) ] Parker, Ashley (NIH/OD) [E] [ (b) (6) ] Perlmutter, Roger [ (b) (6) ] Plenge, Robert [ (b) (6) ]; Plump, Andy [ (b) (6) ] Rachel Ramoni [ (b) (6) ] Reese, David [ (b) (6) ] Rouse, Doris [ (b) (6) ] Santos, Michael (FNIH) [T] [ (b) (6) ] Skovronsky, Daniel [ (b) (6) ] Stein, Peter (FDA/CDER) [ (b) (6) ] Stoffels, Paul [ (b) (6) ]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael [ (b) (6) ] Tsai, John [ (b) (6) ] Vessey, Rupert [ (b) (6) ]; Virgin, Skip [ (b) (6) ] Wholley, David (FNIH) [T] [ (b) (6) ] Woodcock, Janet (FDA/CDER) [ (b) (6) ] Young, John [ (b) (6) ] Colvis, Christine (NIH/NCATS) [E] [ (b) (6) ]; Eric Hughes [ (b) (6) ] Jansen, Kathrin [ (b) (6) ] Kurilla, Michael (NIH/NCATS) [E] [ (b) (6) ] Lowy, Douglas (NCI) [ (b) (6) ] Read, Sarah (NIH/NIAID) [E] [ (b) (6) ] Victoria Davey [ (b) (6) ] Bancel, Stephane [ (b) (6) ] Fauci, Anthony (NIH/NIAID) [E] [ (b) (6) ] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Pangalos, Mene [ (b) (6) ] Paul, Steve [ (b) (6) ] Rasi, Guido [ (b) (6) ] Reed, John [ (b) (6) ] Desrosiers, Betsy [ (b) (6) ]  
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(b) (6) ]; Underwood, Nancy [ (b) (6) Zottoli, Jessica  
(b) (6) Plenge, Robert [ (b) (6) Vessey, Rupert [ (b) (6)  
Regan, Donna M (b) (6) Sorosa, Alex [ (b) (6) Connelly, Sarah  
(b) (6) Lowy, Douglas (NIH/NCI) [E] [ (b) (6) ]; John Lepore  
(b) (6) Grant, Sarah [ (b) (6) Qashu, Felicia (NIH/OD) [E]  
(b) (6) ]; Wachtel, Jonathan (b) (6) Hamilton, Nancy  
(b) (6)

**Subject:** ACTIV Leadership Call #10

**Location:** <https://fnih.zoom.us/> (b) (6)

**Start:** 11/19/2020 5:00:00 PM

**End:** 11/19/2020 6:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; (b) (6) Davey, Victoria

**Optional Attendees:** Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Appell, Evan; Chen, Helen; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfield, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Peralta, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggan, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Plenge, Robert; Hamilton, Nancy; Vessey, Rupert; Regan, Donna M; Sorosa, Alex; Connelly, Sarah; Lowy, Douglas (NIH/NCI) [E]; John Lepore; Grant, Sarah; Qashu, Felicia (NIH/OD) [E]

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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 5/30/2020 12:33:03 AM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]  
**CC:** Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]  
**Subject:** RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi Francis,

Back to you in moments.

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: (b) (6) | Mobile: (b) (6)

---

**From:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Sent:** Friday, May 29, 2020 8:32 PM  
**To:** Wholley, David (FNIH) [T] <(b) (6)>  
**Cc:** Adam, Stacey (FNIH) [T] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Gonzalez, Nina <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)>  
**Subject:** RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Hoping these are coming to me soon, as I may want to do some editing -- and then I wanted to run them past Janet tonight.

FC

---

**From:** Wholley, David (FNIH) [T] (b) (6)  
**Sent:** Friday, May 29, 2020 7:41 PM  
**To:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Cc:** Adam, Stacey (FNIH) [T] (b) (6); Freire, Maria (FNIH) [T] (b) (6); Gonzalez, Nina (b) (6); Parker, Ashley (NIH/OD) [E] (b) (6) Freire, Maria (FNIH) [T]  
**Subject:** RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Have seen and offered a few changes to the complete slide deck. They should be coming back to you as soon as Deloitte makes the changes.

---

**From:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Sent:** Friday, May 29, 2020 5:59 PM



**To:** Wholley, David (FNIH) [T] (b) (6)  
**Cc:** Adam, Stacey (FNIH) [T] (b) (6); Freire, Maria (FNIH) [T] (b) (6); Gonzalez, Nina (b) (6); Parker, Ashley (NIH/OD) [E] <(b) (6)>  
**Subject:** RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi all,

I have received information from Amy Patterson about the anticoagulant trial, and I'd like to have that incorporated into the slide set that Deloitte is currently working on. Attached is the document from Amy. I have highlighted the main points that I would want to have included in the slides, trying if possible to mirror the same features that are going to be included in the description of the immunomodulator study.

See what you think. I stand ready to look at ppts anytime this evening.

One question about the immunomodulator trial that I noticed in Moncef's note – has FDA agreed with the plan to move straight into phase 3 from a safety and efficacy standpoint?

Thanks, Francis

---

**From:** Wholley, David (FNIH) [T] (b) (6)  
**Sent:** Friday, May 29, 2020 1:59 PM  
**To:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Cc:** Adam, Stacey (FNIH) [T] (b) (6); Freire, Maria (FNIH) [T] <(b) (6)>; Gonzalez, Nina (b) (6); Parker, Ashley (NIH/OD) [E] (b) (6)  
**Subject:** Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Francis:

Here is the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1; it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
- OWS/ACTIV Therapeutics has been taking a **portfolio** approach to addressing the dramatic health and economic challenges posed by the pandemic, with harmonized efforts that address both disease etiology and symptomology.
  - ACTIV Baricitinib (ACTT2, sponsored by NIAID) – in progress
  - ACTIV hiVIG (sponsored by NIAID) - in progress
  - ACTIV-1 – Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) – (Phase III) – ready to launch late June
  - ACTIV-2\* – Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) – (Phase II/III) – projected launch June
  - ACTIV-3\* – Neutralizing Monoclonal Antibodies Inpatient Master Protocol (NIAID INSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/III) – projected launch July
  - ACTIV-4 – Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually, Anticoagulant+Immune Modulator Combinations (NHLBI-NINDS "Master" Network) – (Phase II/III) – projected launch late June

- ACTIV-5 – De Novo Master Protocol Structure to test promising agents not effectively evaluated elsewhere (e.g., antivirals) – similar design to the mAb protocols, networks/sites/agents in discussions now – projected launch August (*if needed; i.e. if agents are not incorporated into mAb protocols*)  
\* current priority  
[for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base]
- Prioritization Process (v 2.0) for ACTIV : (slide 14 from May 20 EC deck)
- Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)  
[Key Criteria for Scoring (slide 15 from 5/20) can go to backup]
- Prioritization and Protocol Design: Who is Involved – two-box slide containing names and affiliations of those involved in the Prioritization and MP Subgroups (quality folks!)
- ACTIV-1 Protocol for immunomodulators
  - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)
  - 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
  - All 3 either have initial Phase II data or are currently running company-sponsored Phase II trials = high POS
  - Phase III master protocol design for ACTIV-1 includes aggressive efficacy and futility assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)
  - Companies have agreed to share data + common control arm + common endpoints + DSMB = efficiency and ability to compare results across arms (this does not happen if companies test separately)
  - Protocol is 80% complete
    - Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
      - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)
    - All three companies have written their sections of the protocols, which are being merged into the master design
  - Working with OWS/BARDA on choice of CRO to run the trial; (b) (5)
- “ACTIV-4” Protocol for anticoagulants
  - Need bullets from NHLBI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS “network of networks” with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the clinical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley  
Senior Vice-President, Research Partnerships  
Foundation for the National Institutes of Health

(b) (6)

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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 5/27/2020 12:00:04 AM  
**To:** Eric Hughes [ (b) (6) ] Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [ (b) (6) ] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [ (b) (6) ] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [ (b) (6) ] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [ (b) (6) ] Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [ (b) (6) ] Keith Gottesdiener [ (b) (6) ] Elliott Levy [ (b) (6) ] Wung, Peter /US [ (b) (6) ] Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [ (b) (6) ] Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]  
**CC:** Elizabeth Kim [ (b) (6) ] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [ (b) (6) ] Salathin, Carla [ (b) (6) ] [ (b) (6) ] [ (b) (6) ] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [ (b) (6) ] Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [ (b) (6) ] Chen, Helen Q. [ (b) (6) ]  
**Subject:** Inquiry about the ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #13

Dear ACTIV Agent Prioritization Subgroup,

It has become apparent that our mAb Prioritization Subteam will need to have a second meeting this week.

Since we are still working on getting back the data requested for this larger team, I was hoping this group would allow us to cancel this larger meeting and use the time to have just a meeting of our mAb Prioritization Subteam.

This group will get an overall update on the progress of the TX-Clinical WG at our large WG meeting with both the Agent Prioritization and Master Protocol teams, and we will work to get individual meetings for the other Agent Prioritization Subteams on the books for next week if the data has been fully assembled.

**Please let me know if you have any opposition to canceling the meeting to allow for the smaller group meeting.** If a majority would prefer to keep the meeting, we will find another time for the small group.

Thanks,  
Stacey



Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 6/6/2020 5:00:32 PM  
**To:** Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]  
**Subject:** RE: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures  
**Attachments:** iTPP COVID-19 mAb PREP PEP \_\_Exec Summ.docx; iTPP COVID-19 mAb Treatment\_Exec Summ.docx  
  
**Flag:** Follow up

Hi Joe and Francis,

Did not receive anything ahead of time. This was planned on such short notice. We did not have time to get something from her, but I can give both these mAb criteria that they shared with our WG.

Thanks,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnerships  
Direct: (b) (6) | Mobile: (b) (6)

---

**From:** Menetski, Joseph (FNIH) [T] <(b) (6)>  
**Sent:** Saturday, June 6, 2020 12:55 PM  
**To:** Collins, Francis (NIH/OD) [E] <(b) (6)> ; Wholley, David (FNIH) [T] <(b) (6)> ; Adam, Stacey (FNIH) [T] <(b) (6)> ; Melencio, Cheryl (FNIH) [T] <(b) (6)> ; Wood, Gretchen (NIH/OD) [E] <(b) (6)>  
**Cc:** Adam, Stacey (FNIH) [T] <(b) (6)>  
**Subject:** RE: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

Not that I can see.

Did anyone else get any, David?

Joe

---

**From:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Sent:** Saturday, June 6, 2020 12:53 PM  
**To:** Menetski, Joseph (FNIH) [T] (b) (6) ; Wholley, David (FNIH) [T] <(b) (6)> ; Adam, Stacey (FNIH) [T] (b) (6) ; Melencio, Cheryl (FNIH) [T] (b) (6) >; Wood, Gretchen (NIH/OD) [E] (b) (6)  
**Cc:** Adam, Stacey (FNIH) [T] (b) (6)  
**Subject:** RE: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

OK. Did we get any read-ahead material from Jacqueline?

---

**From:** Menetski, Joseph (FNIH) [T] (b) (6)  
**Sent:** Saturday, June 6, 2020 12:53 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6) >; Wholley, David (FNIH) [T] < (b) (6) >; Adam, Stacey (FNIH) [T] < (b) (6) >; Melencio, Cheryl (FNIH) [T] (b) (6) ; Wood, Gretchen (NIH/OD) [E] < (b) (6) >  
**Cc:** Adam, Stacey (FNIH) [T] (b) (6)  
**Subject:** RE: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

Dear Francis,

The meeting has these invites.

Wholley, David (FNIH) [T]  
Adam, Stacey (FNIH) [T]  
Menetski, Joseph (FNIH) [T]  
Jacqueline Kirchner  
Woodcock, Janet (FDA/CDER)  
Collins, Francis (NIH/OD) [E]

joe

---

**From:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Sent:** Saturday, June 6, 2020 12:50 PM  
**To:** Wholley, David (FNIH) [T] (b) (6) >; Menetski, Joseph (FNIH) [T] (b) (6) >; Adam, Stacey (FNIH) [T] (b) (6) >; Melencio, Cheryl (FNIH) [T] (b) (6) ; Wood, Gretchen (NIH/OD) [E] < (b) (6) >  
**Cc:** Menetski, Joseph (FNIH) [T] (b) (6) ; Adam, Stacey (FNIH) [T] (b) (6)  
**Subject:** RE: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

Sincere apologies, I just saw this message. I don't know who has been invited to join this call, can someone fill me in?

---

**From:** Wholley, David (FNIH) [T] (b) (6)  
**Sent:** Saturday, June 6, 2020 7:21 AM  
**To:** Menetski, Joseph (FNIH) [T] (b) (6) ; Collins, Francis (NIH/OD) [E] < (b) (6) >; Adam, Stacey (FNIH) [T] < (b) (6) >; Melencio, Cheryl (FNIH) [T] < (b) (6) >; Wood, Gretchen (NIH/OD) [E] (b) (6)  
**Cc:** Menetski, Joseph (FNIH) [T] <jm (b) (6) >; Adam, Stacey (FNIH) [T] (b) (6) >  
**Subject:** Re: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

I noticed a label on today's call "data shared in confidence". Does this give us pause in terms of inviting additional experts?

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---

**From:** Menetski, Joseph (FNIH) [T] < (b) (6) >  
**Sent:** Friday, June 5, 2020 6:43:53 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Wholley, David (FNIH) [T] (b) (6) ; Menetski, Joseph (FNIH) [T] < (b) (6) >; Adam, Stacey (FNIH) [T] <sadam@fnih.org>  
**Subject:** Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

COLL0000017549-2516985



Dear Francis,

Stacey and I have polled our working groups, asking for suggestions and volunteers that could provide expert opinion on monoclonal antibody testing during conversations with Skip Virgin and Jacqueline Kirchner. The groups are very enthusiastic about this topic and we received almost 30 names of experts in the field. Given the time frame that we are asking for people to join these calls, I have picked 4 people that are already involved in ACTIV to invite to the Jacqueline Kirchner call tomorrow and 6 to invite to the call with Skip on Monday.

As I said, there were many more, but I think we would want to talk to them first, before bringing them into a discussion like this.

I am happy to invite these folks tonight, if it would be easier and agreeable to you (I would cc you). Or I have drafted a short email for you to send them below (as always, feel free to modify).

Best regards,  
Joe

---

Memo: ACTIV discussion on choosing neutralizing antibodies and mixtures

Dear xx,

The NIH Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership is setting up protocols to assess monoclonal neutralizing antibodies as therapies against COVID-19. During discussions with the ACTIV Leadership Team and in collaboration with the upcoming Monoclonal Antibody Round Table, we have a meeting to gather additional expert opinion on the appropriate preclinical testing approaches, particularly for choosing mixtures or cocktails of neutralizing Abs. I would like to have your input in the important topic during a meeting [tomorrow at 1pm ET; or Monday at 2:45pm ET]. I realize this is short notice, but the ACTIV program is moving very fast and our rapid response is essential. I hope you can join me in this important discussion.

Sincerely,  
Francis Collins

**Names and emails below.**

*Saturday call with J Kirchner:*

Peter Adams, (OS/ASPR/BARDA); (b) (6)

Michael Diamond at Washington University at St Louis; (b) (6)

Kara Carter at EvoTec; (b) (6)

John W Mellors at University of Pittsburgh; (b) (6)

*Monday call with Skip Virgin:*

Peter Adams, (OS/ASPR/BARDA); (b) (6)

Michael Diamond at Washington University at St Louis; (b) (6)

Kara Carter at EvoTec; (b) (6)

John W Mellors at University of Pittsburgh; (b) (6)

Randall Tressler, (NIH/NIAID); (b) (6)

Sebastian Breuer, Roche; (b) (6)

Joseph P. Menetski Ph.D.  
Associate Vice President, Research Partnerships  
Foundation for the National Institutes of Health

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(b) (6)

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**From:** (b) (6)  
**Sent:** 10/10/2020 6:30:56 PM  
**To:** Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]  
**CC:** Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]  
**Subject:** Re: Roster of ACTIV Vaccines WG

Can you do me a favor and just pull out the names and institutions of the people who are not on the Vaccines WG?

Sent from my iPhone

On Oct 10, 2020, at 2:21 PM, Santos, Michael (FNIH) [T] <(b) (6)> wrote:

Hi Francis,

We don't maintain as nice of a version of the Sub-Group rosters, but here is the Clinical Trials Sub-Group list of names and organizations (some of which overlap with the main WG). We also commonly have additional guests depending on the topic, so if there's an organization or expertise that you're looking for that is not represented, we can invite them to a meeting ad hoc.

Thanks,  
Mike

Name	Organization
Paula Annunziato (co-chair)	Merck
Larry Corey (co-chair)	Fred Hutch
Ann Arvin	Stanford
Beth Bell	UW
Marco Cavaleri	EMA
Myron Cohen	UNC
Elizabeth Desrosiers	Merck
Macaya Douguilh	J&J
Peter Dull	Gates
Emilio Emini	Gates
Emily Erbeling	NIAID/NIH
Gregory M. Glenn	Novavax
Peter Gilbert	SCHARP/UW
Paul Gillard	GSK
Bill Gruber	Pfizer
Marion Gruber	CBER/FDA
Sanjay Gurunathan	Sanofi



Holli Hamilton	BARDA
Ian Hirsch	AZ
Peter Hotez	Baylor and Texas Children's
Laurent Humeau	Inovio
Kathrin Jansen	Pfizer
Cheryl Keech	Novavax
Kenneth Koury	Pfizer
Michael Kurilla	NCATS/NIH
Julie Ledgerwood	NIAID/NIH
Maarten Leyssen	J&J
Doug Lowy	NCI/NIH
Peter Marks	CBER/FDA
Mary Marovich	NIAID/NIH
Hilary Marston	NIAID/NIH
Stacey Martin	CDC
John Mascola	VRC/NIH
Nelson Michael	WRAIR
Jacqueline Miller	Moderna
Kayvon Modjarrad	WRAIR
Kathleen Neuzil	Maryland
Paul Offit	Penn/CHOP
Ashley Parker	NIH
Merlin Robb	Henry Jackson Foundation
François Roman	GSK
Jerald Sadoff	J&J
Stephanie Schrag	CDC
Sheri Schully	NIH
Sandra Sitar	VRC/NIH
Saranya Sridhar	Sanofi
Jennifer Verani	CDC
Michael Watson	Moderna
Tal Zaks	Moderna

**Michael Santos, PhD**

Associate Vice President, Science | Foundation for the National Institutes of Health

---

**From:** Collins, Francis (NIH/OD) [E] < > (b) (6)

**Sent:** Saturday, October 10, 2020 12:47 PM

**To:** Santos, Michael (FNIH) [T] < > (b) (6)

**Cc:** Lane, Cliff (NIH/NIAID) [E] < > (b) (6) Wholley, David (FNIH) [T] < > (b) (6)

Freire, Maria (FNIH) [T] < > (b) (6)

**Subject:** RE: Roster of ACTIV Vaccines WG

Thanks, this is helpful. Have you got a roster of the Clinical Trials Sub-Group?

COLL0000011176-2516986

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**From:** Santos, Michael (FNIH) [T] <(b) (6)>  
**Sent:** Saturday, October 10, 2020 11:47 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Wholley, David (FNIH) [T] (b) (6) ;  
Freire, Maria (FNIH) [T] (b) (6)  
**Subject:** RE: Roster of ACTIV Vaccines WG

Hi Francis,

Sure, I'd be happy to convene a meeting of the WG.

The WG membership is attached. We also have a wider group of people that have been part of the sub-groups, so depending on the topic and the ask we could invite them as well (e.g., for a clinical trials question we could convene the WG plus the Clinical Trials Sub-Group).

For next steps, if we can know a little more about the topic and the desired timing, I'm happy to connect with Kathrin and Doug and schedule a meeting with the appropriate set of people.

Best regards,  
Mike

Michael Santos, PhD  
Associate Vice President, Science | Foundation for the National Institutes of Health

---

**From:** Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>  
**Sent:** Saturday, October 10, 2020 11:33 AM  
**To:** Santos, Michael (FNIH) [T] <(b) (6)>  
**Cc:** Lane, Cliff (NIH/NIAID) [E] <(b) (6)>; Wholley, David (FNIH) [T] <dwhol (b) (6)>  
Freire, Maria (FNIH) [T] <(b) (6)>  
**Subject:** Roster of ACTIV Vaccines WG

Hi Mike,

We might need to reconvene the ACTIV Vaccines WG for some advice about management of next steps for the trials. Can you send me the roster?

Francis

---

**From:** Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]  
**Sent:** 10/18/2020 10:54:09 PM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]  
**Subject:** RE: Need advice about presentation at a NASEM meeting  
**Flag:** Follow up

Hi Francis:

Lisa LaVange is currently with UNC, but formerly a statistician with FDA, has done lots of work in cancer supporting Rick Pazdur and Janet Woodcock including on LungMAP—Ellen Sigal is a big fan by the way. From an ACTIV perspective Lisa has been an integral member of the overall Tx-Clinical Working Group, of the Master Protocol subgroup, and of the MP Statistics subgroup as these various entities have been assembled since April. Lisa has been absolutely integral to informing the statistical design of the ACTIV-1, -2, and -3 protocols, and has reviewed the other two protocols, in collaboration with Mike Proschan of NIAID, Sylvia Collins of FDA, and others. I have heard her on many calls I have attended, and in my experience Lisa navigates among the frequentist and Bayesian approaches nimbly and without taking a dogmatic approach. She is articulate and always pleasant and collegial to deal with.

If that sounds like a five-star review, I guess it is.

I defer to Cliff and others on the comparison to RECOVERY, but have asked Stacey Adam for a few bullets.

I leave the question regarding the antiviral summit to Jim and others.

Thanks, David

---

**From:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Sent:** Sunday, October 18, 2020 4:57 PM  
**To:** Wholley, David (FNIH) [T] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Anderson, James (NIH/OD) [E] <(b) (6)>  
**Subject:** Need advice about presentation at a NASEM meeting

Hi there War Roomies,

As you can see from the attached, the NASEM Forum on Drug Discovery, Development, and Translation is putting on a two day virtual meeting. Part of the first day is to hear about ACTIV, and compare and contrast that with RECOVERY. I could use your advice about what to include in my 15 minutes. Your assessment of the pros and cons of the RECOVERY trial design and implementation would be welcome. And can you remind me what role Lisa LaVange has played in ACTIV?



Would this be a good opportunity to highlight the coming workshop on antivirals? Or would that be premature?

Francis



(NIH/NCATS) [E] (b) (6) ; Bryant, Paula (NIH/NIAID) [E] < (b) (6)  
**Cc:** (b) (6) antoinette\_baric  
(b) (6) >; Micheloni, Gianni < (b) (6) Soren, Daniel (NIH/NLM/NCBI)  
[C] (b) (6)  
**Subject:** RE: ACTIV - Emerging Viral Sequence Data Surveillance, Testing and Reporting

Dear Subgroup Members,

Thank you all for attending our Emerging Viral Sequence subgroup meeting on Tuesday. Please see attached for the notes from our discussion, and let us know if you all have any additions or amendments.

Best Regards,  
Sarah

**Sarah Connelly, PhD**  
Deloitte Consulting, LLP  
Tel/Direct: +1 (b) (6)  
[www.deloitte.com](http://www.deloitte.com)

-----Original Appointment-----

**From:** Connelly, Sarah

**Sent:** Wednesday, December 23, 2020 11:12 AM

**To:** Connelly, Sarah; (b) (6)

(b) (6)

(b) (6) Hawk, Harrison; Menetski, Joseph (FNIH) [T]; MacCannell, Duncan  
(CDC/DDID/NCEZID/OD); FNIH; (b) (6); Stapleton, Jack; Phillips, L Revell CIV DTRA RD (USA); Qashu,  
Felicia (NIH/OD) [E]; Nancy Haigwood; Dormitzer, Philip Ralph; Jansen, Kathrin; (b) (6);  
rol (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher, Katie; (b) (6);  
(b) (6) Lorraine Horgan; Li Yan; Qing Zhu; (b) (6);  
(b) (6); Andrew Charles Adams; Esser, Mark; David Margolis; (b) (6);  
(b) (6) Eastman, Richard (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Brimacombe, Kyle  
(NIH/NCATS) [E]; (b) (6);  
(b) (6); Baric, Toni C; Micheloni, Gianni;  
Soren, Daniel (NIH/NLM/NCBI) [C]

**Subject:** ACTIV - Emerging Viral Sequence Data Surveillance, Testing and Reporting

**When:** Tuesday, January 26, 2021 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).

**Where:** <https://deloitte.zoom>. (b) (6)

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**From:** Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]  
**Sent:** 7/15/2020 5:38:22 PM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]  
**Subject:** FW: ACTIV Vaccines Working Group meeting  
**Location:** Webex: <https://nih.webex.com/> (b) (6)  
**Start:** 7/29/2020 2:00:00 PM  
**End:** 7/29/2020 3:00:00 PM  
**Show Time As:** Tentative

-----Original Appointment-----

**From:** Santos, Michael (FNIH) [T] <(b) (6)>  
**Sent:** Tuesday, June 30, 2020 3:18 PM  
**To:** Santos, Michael (FNIH) [T]; (b) (6) Lowy, Douglas (NIH/NCI) [E]; Arvin, Ann; Beth Bell (b) (6) (b) (6) Cavaleri Marco; (b) (6) (b) (6) (b) (6) Greg Glenn; (b) (6) Haynes, Barton; (b) (6) (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; Seals, Jonathan (OS/ASPR/BARDA); (b) (6) (b) (6) Tal Zaks; (b) (6) (b) (6)  
**Cc:** Tolman, Brett; (b) (6) Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen (NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker, Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Paul Gillard; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; 'Wachtel, Jonathan'; Stratton, Benjamin; Anderson, Margaret; (b) (6) (b) (6) Bethany Stokes; Kathleen Callahan; Arvin, Ann; Young, John  
**Subject:** ACTIV Vaccines Working Group meeting  
**When:** Wednesday, July 29, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).  
**Where:** Webex: <https://nih.webex.com/> (b) (6)

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**From:** Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]  
**Sent:** 3/21/2021 3:54:35 PM  
**To:** Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]  
**CC:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]  
**Subject:** RE: ACTIV Leadership Team Call #14

**Flag:** Follow up

Yes, sorry, I was aware but just missed this one.

---

**From:** Tabak, Lawrence (NIH/OD) [E] <(b) (6)>  
**Sent:** Sunday, March 21, 2021 11:53 AM  
**To:** Wholley, David (FNIH) [T] <(b) (6)>  
**Subject:** Re: ACTIV Leadership Team Call #14

David;  
Going forward, please swap Joni Rutter for Chris. Chris is recused from all ACTIV effort.  
Thanks  
Larry

---

**From:** Wholley, David (FNIH) [T] <(b) (6)>  
**Date:** Sunday, March 21, 2021 at 11:51 AM  
**To:** Melencio, Cheryl (FNIH) [T] <(b) (6)>, Austin, Christopher (NIH/NCATS) [E] <(b) (6)>, Carter, Kara (b) (6) <(b) (6)>, Cavaleri, Marco <(b) (6)>, Cihlar, Tomas <(b) (6)>, Collins, Francis (NIH/OD) [E] <(b) (6)>, Corey, Larry <(b) (6)>, Culp, Michelle (NIH/OD) [E] <(b) (6)>, Victoria Davey <(b) (6)>, Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)>, Dolsten, Mikael <(b) (6)>, Erbeling, Emily (NIH/NIAID) [E] <(b) (6)>, Erck, Stan <(b) (6)>, Gadbois, Ellen (NIH/OD) [E] <(b) (6)>, Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)>, Hudson, Thomas <(b) (6)>, James, Stephanie (FNIH) [T] <(b) (6)>, Johnson, Robert (OS/ASPR/BARDA) <(b) (6)>, Kramer, Lynn <(b) (6)>, Lane, Cliff (NIH/NIAID) [E] <(b) (6)>, Mascola, John (NIH/VRC) [E] <(b) (6)>, Meeker, David <(b) (6)>, Menetski, Joseph (FNIH) [T] <(b) (6)>, Messonnier, Nancy (CDC/DDID/NCIRD/OD) <(b) (6)>, Pandya, Hitesh <(b) (6)>, Pao, William <(b) (6)>, Parker, Ashley (NIH/OD) [E] <(b) (6)>, Perlmutter, Roger <(b) (6)>, Plenge, Robert <(b) (6)>, Plump, Andy <(b) (6)>, Reese, David <(b) (6)>, Rouse, Doris <(b) (6)>, Santos, Michael (FNIH) [T] <(b) (6)>, Skovronsky, Daniel <(b) (6)>, Stein, Peter (FDA/CDER) <(b) (6)>, Stoffels, Paul <(b) (6)>, Tabak, Lawrence (NIH/OD) [E] <(b) (6)>, Talley, Michael <(b) (6)>, Tsai, John <(b) (6)>, Vessey, Rupert <(b) (6)>, Virgin, Skip <(b) (6)>, Woodcock, Janet (FDA/OC) <(b) (6)>, Young, John <(b) (6)>, Anderson, James (NIH/OD) [E] <(b) (6)>, Burklow, John (NIH/OD) [E] <(b) (6)>, Carluccio, Dana <(b) (6)>, Castillejos, Carlos <(b) (6)>, FNIH Central Account <(b) (6)>, Hallett, Adrienne (NIH/OD) [E] <(b) (6)>, Lumsden, Joanne (NIH/NCATS) [C] <(b) (6)>, Myles, Renate (NIH/OD) [E] <(b) (6)>, Wolinetz,

Carrie (NIH/OD) [E] < (b) (6) Colvis, Christine (NIH/NCATS) [E] (b) (6)  
 Desrosiers, Betsy (b) (6) Eric Hughes (b) (6) Jansen,  
 Kathrin (b) (6) Kurilla, Michael (NIH/NCATS) [E] < (b) (6) Lowy,  
 Douglas (NCI) < (b) (6) Read, Sarah (NIH/NIAID) [E] (b) (6) Meltzer, Abbey (FNIH)  
 [T] < (b) (6) Adam, Stacey (FNIH) [T] (b) (6) , Margaret Anderson  
 < (b) (6) Appell, Evan < (b) (6) Chen, Helen  
 ( >, Connelly, Sarah (b) (6) Gonzalez, Nina  
 b (b) (6) , Hawk, Harrison (b) (6) >, Mendelson, Jesse  
 < (b) (6) Nasr, Hana (b) (6) Sorosa, Alex (b) (6) >,  
 Stratton, Benjamin < (b) (6) >, Tolman, Brett <(b) (6) >, Wachtel, Jonathan  
 < (b) (6) Embry, Alan (NIH/NIAID) [E] < (b) (6) Venkayya, Rajeev  
 (b) (6) < (b) (6) Bancel, Stephane  
 (b) (6) , Fauci, Anthony (NIH/NIAID) [E] (b) (6) Lepore, John  
 < (b) (6) Marks, Peter (FDA/CBER) < (b) (6) Pangalos, Mene  
 (b) (6) Paul, Steve < (b) (6) Rachel Ramoni  
 (b) , Reed, John (b) (6)  
 Cc: Austin, Sarah (NIH/NIAID) [E] < (b) (6) Barasch, Kimberly (NIH/NIAID) [E]  
 < (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] (b) (6) , Carver, Trea  
 (NIH) [C] (b) (6) >, Caulfied, Anita < (b) (6) , Coan, Amanda  
 < (b) (6) Conrad, Patricia (NIH/NIAID) [E] < (b) (6) Dimishkov, Roxanne  
 (NIH/NHLBI) [C] < (b) (6) Edl, Susan < (b) (6) Fuhrer, Nicole  
 < (b) (6) Giorgi, Sara (b) (6) Hoban, Michelle  
 < (b) (6) Hoffstetter, Renata (FNIH) [T] (b) (6) >, Iberdemaj, Vaide  
 < (b) (6) Jenkins, Christine S. (b) (6) >, Lagos, Enrique  
 (NIH/NCATS) [E] (b) (6) , Lever, Susan (b) (6) Magbie-Robinson,  
 Kim (NIH/OD) [C] < (b) (6) Martin, Melisa < (b) (6) McManus, Ayanna  
 (NIH/OD) [E] (b) (6) Minnich, Beth < (b) (6) Perala, Mie  
 (b) (6) Protasiewicz, Ann < (b) (6) Riccobene, Kim  
 < (b) (6) Riffin, Mary < (b) (6) Ripley, Nadege  
 < (b) (6) Schuster, Donna (b) (6) Sepulveda, Dorina (FNIH)  
 [T] (b) (6) Simon, Dina (NIH/OD) [C] < (b) (6) Suhana, Tina (NIH/VRC) [E]  
 (b) (6) >, Thomas, Ashley (FDA/CDER) <As (b) (6) Wood, Gretchen  
 (NIH/OD) [E] (b) (6) , Hughes, Karen (NIH/OD) [E] < (b) (6) Togashi, Mieko  
 (NIH/NCI) [E] < (b) (6) Underwood, Nancy <nancy (b) (6) Zottoli,  
 Jessica (b) (6) Regan, Donna M < (b) (6) Vessey, Rupert  
 (b) (6) Burke, Leslie (b) (6) John Lepore  
 (b) (6) >, Lowy, Douglas (NIH/NCI) [E] (b) (6) Grant, Sarah  
 (b) (6) >, Pruitt, Kim (NIH/NLM/NCBI) [E] < (b) (6) Sherry, Steve  
 (NIH/NLM/NCBI) [E] (b) (6) Bell, Julie (b) (6)

**Subject:** RE: ACTIV Leadership Team Call #14

Dear ACTIV Leadership Team members and meeting attendees:

Please find attached the notes from our meeting this past Thursday, March 18, 2021. Please let me know if you have any questions or additional comments, and thank you for your participation in the call.

Regards,

David



**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
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Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [ (b) (6) Petrovick, Martha - 0449 - MITLL [ (b) (6) (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]

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**Subject:** Slides from the ACTIV Therapeutics-Clinical Working Group Meeting

**Attachments:** ACTIV\_TX-Clinical\_Working Group Meeting Guide\_20200902.pdf; CONNECTS SHORT overview for ACTIV Clin Tx WG 090220 FINAL.pdf

Dear ACTIV TX-Clinical WG Members,

As promised earlier today, please find attached the slides from our presentations today.

Thanks,  
Stacey

**Stacey J. Adam, PhD**

Director, Cancer

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**From:** Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]  
**Sent:** 1/17/2021 5:18:46 PM  
**To:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Carter, Kara [ (b) (6) Cavaleri, Marco (b) (6) Cihlar, Tomas (b) (6) ; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [ (b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [ (b) (6) Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Erck, Stan [ (b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [ (b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [ (b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [ (b) (6) ]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Pandya, Hitesh [ (b) (6) Pao, William [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Perlmutter, Roger [ (b) (6) Plenge, Robert [ (b) (6) Plump, Andy [ (b) (6) Rouse, Doris [ (b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [ (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael [ (b) (6) Tsai, John [ (b) (6) Vessey, Rupert [ (b) (6) Virgin, Skip [ (b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [ (b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group



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(b) (6) Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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(b) (6) Bancel, Stephane [ (b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group  
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(b) (6) Reese, David [ (b) (6) Stoffels, Paul [ (b) (6) Desrosiers, Betsy  
(b) (6)  
CC: Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Caulfied, Anita  
(b) (6) Coan, Amanda [ (b) (6) Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Edl, Susan



[ (b) (6) Fuhrer, Nicole [ (b) (6) Giorgi, Sara [ (b) (6) Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter]; Iberdemaj, Vaide [ (b) (6) Jenkins, Christine S. [ (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Lever, Susan [ (b) (6) Martin, Melisa [ (b) (6) McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Minnich, Beth [ (b) (6) Perala, Mie [ (b) (6) Protasiewicz, Ann [ (b) (6) Riccobene, Kim [ (b) (6) Riffin, Mary [ (b) (6) Ripley, Nadege [ (b) (6) Schuster, Donna [ (b) (6) Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Suhana, Tina (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e062bf05a14748ba3d9fbb3e468057-esuhana]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Togashi, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Underwood, Nancy [ (b) (6) Zottoli, Jessica [ (b) (6) Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Tajalli, Ada (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4fd4747b0d954e27855c241b28562547-tajallian]; Regan, Donna M [ (b) (6) Magbie-Robinson, Kim (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74a5b9cea10b4f919d9db20c8aaec3e7-magbierobin]; Vessey, Rupert [ (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Ellis, Carol [ (b) (6) ]; Bell, Julie [ (b) (6) Hoban, Michelle [ (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

**Subject:** RE: ACTIV Leadership/EC Call #12

**Attachments:** 2021-01-14\_ACTIV\_Leadership\_Team\_and\_Executive\_Committee\_Meeting\_Summary\_vF.pdf

Dear ACTIV Executive Committee and Leadership Team members, and meeting attendees:

Attached please see the minutes from our meeting this past Thursday, January 14, 2021. As always please let me know if you have any additional comments or questions.

Regards,  
David Wholley



**From:** Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]  
**Sent:** 11/12/2020 5:10:25 PM  
**To:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Bancel, Stephane [ (b) (6) Carter, Kara [ (b) (6) Cavaleri, Marco [ (b) (6) Cihlar, Tomas [ (b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [ (b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [ (b) (6) Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Erck, Stan [ (b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [ (b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [ (b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John [ (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [ (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Pandya, Hitesh [ (b) (6) Pangalos, Mene [ (b) (6) Pao, William [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Paul, Steve [ (b) (6) Perlmutter, Roger [ (b) (6) Plenge, Robert [ (b) (6) Plump, Andy [ (b) (6) Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Rasi, Guido [ (b) (6) Reed, John [ (b) (6) Reese, David [ (b) (6) Rouse, Doris [ (b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [ (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [ (b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael [ (b) (6) Tsai, John [john. [ (b) (6) Vessey, Rupert [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John



(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]

CC: Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Carluccio, Dana [dana.carluccio@roseliassociates.com]; Castillejos, Carlos [ (b) (6) FNIH Central Account [ (b) (6) Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mendelson, Jesse [ (b) (6) asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) Gorman, Greta (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Bell, Julie [julie.bell@astrazeneca.com]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Caulfied, Anita [ (b) (6) Coan, Amanda [ (b) (6) Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Edl, Susan [ (b) (6) Fuhrer, Nicole [ (b) (6) Giorgi, Sara [ (b) (6) Hoban, Michelle [ (b) (6) Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter];



Iberdemaj, Vaide [ (b) (6) Jenkins, Christine S. [ (b) (6) Krack, Kimberly [kimberly]; (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Lever, Susan [ (b) (6) McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Minnich, Beth [ (b) (6) Perala, Mie [ (b) (6) Protasiewicz, Ann [ (b) (6) Riccobene, Kim [ (b) (6) Riffin, Mary [ (b) (6) Ripley, Nadege [ (b) (6) Schuster, Donna [ (b) (6) Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Suhana, Tina (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e062bf05a14748ba3d9fbb3e468057-esuhana]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Tajalli, Ada (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4fd4747b0d954e27855c241b28562547-tajallian]; Togashi, Mieke (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Underwood, Nancy [ (b) (6) Zottoli, Jessica [ (b) (6)

**Subject:** ACTIV Leadership Team Meeting #11

**Location:** <https://fnih.zoom.us/> (b) (6)

**Start:** 12/16/2020 3:00:00 PM

**End:** 12/16/2020 4:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]

**Optional Attendees:** Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfied, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riffin, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina

(NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Hughes, Karen (NIH/OD) [E]; Tajalli, Ada (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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**From:** Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]  
**Sent:** 4/18/2020 8:48:03 PM  
**To:** Bascles, Lionel [ (b) (6) ] Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron\_cohen]; Corey, Larry [ (b) (6) ] Desrosiers, Betsy [ (b) (6) ] Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [ (b) (6) ] Srinivasan, Badhri [ (b) (6) ] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Vincent, Mike [ (b) (6) ] Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]  
**CC:** Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [ (b) (6) ] Jansen, Kathrin [ (b) (6) ] Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [ (b) (6) ] Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [ (b) (6) ] Carluccio, Dana [ (b) (6) ] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [ (b) (6) ] James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [ (b) (6) ] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [ (b) (6) ] Wachtel, Jonathan [ (b) (6) ]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [ (b) (6) ] Hamilton, Nancy [ (b) (6) ] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth [ (b) (6) ] Mueller-Reichenstein, Petra [ (b) (6) ] Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Thomas, Ashley (FDA/CDER)

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[C] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]

**Subject:** Clinical Trial Capacity Working Group Meeting #2 Summary

**Attachments:** Clinical\_Trial\_Capacity\_Working\_Group\_Meeting #2\_Summary\_FINAL.pdf

Dear Clinical Trial Capacity Working Group colleagues,

Attached is the Summary of meeting #2 of the Clinical Trial Capacity Working Group. The subgroups are making good headway, so there will be much to report during Tuesday's meeting (April 21, 9:00 am ET USA).

Best regards,

Karen

**Karen H. Tountas, PhD**

Scientific Program Manager

**Foundation for the National Institutes of Health**

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**From:** Lowy, Douglas (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F1B7B8FE4739478BB17840C56902718A-LOWYD]  
**Sent:** 7/3/2020 4:09:15 PM  
**To:** Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]  
**CC:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]  
**Subject:** Re: Gallo and OPV  
**Flag:** Follow up

Thanks, Tony. Can you suggest one or two people with whom I can discuss the issue? Doug

---

**From:** "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)>  
**Date:** Friday, July 3, 2020 at 12:07 PM  
**To:** "Lowy, Douglas (NIH/NCI) [E]" <(b) (6)> "Collins, Francis (NIH/OD) [E]" <(b) (6)> "Lane, Cliff (NIH/NIAID) [E]" <(b) (6)> "Mascola, John (NIH/VRC) [E]" <(b) (6)>  
**Cc:** "Wholley, David (FNIH) [T]" <(b) (6)>  
**Subject:** RE: Gallo and OPV

This issue will not go away and so perhaps it is best to have the ACTIV Vaccines WG take a look at this and make some sort of recommendation.

---

**From:** Lowy, Douglas (NIH/NCI) [E] <(b) (6)>  
**Sent:** Friday, July 3, 2020 11:54 AM  
**To:** Collins, Francis (NIH/OD) [E] <(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Mascola, John (NIH/VRC) [E] <(b) (6)>  
**Cc:** Wholley, David (FNIH) [T] <(b) (6)>  
**Subject:** Re: Gallo and OPV

Hi Francis: The vaccine working group has not discussed this topic. Doug

---

**From:** "Collins, Francis (NIH/OD) [E]" <(b) (6)>  
**Date:** Friday, July 3, 2020 at 11:46 AM  
**To:** "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)> "Lane, Cliff (NIH/NIAID) [E]" <(b) (6)> "Lowy, Douglas (NIH/NCI) [E]" <(b) (6)> "Mascola, John (NIH/VRC) [E]" <(b) (6)>  
**Cc:** "Wholley, David (FNIH) [T]" <(b) (6)>  
**Subject:** RE: Gallo and OPV

Hi Tony, Cliff, Doug, and John (and looping in David)

Bob Gallo is back with a complaint that no one has followed up on the OPV idea. See attached. Was this discussed in the ACTIV Vaccines WG or in any other venue?



Tx, Francis

---

**From:** Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>

**Sent:** Sunday, May 3, 2020 1:45 PM

**To:** Lane, Cliff (NIH/NIAID) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6)

**Cc:** Lowy, Douglas (NIH/NCI) [E] (b) (6); Mascola, John (NIH/VRC) [E] (b) (6)

**Subject:** RE: Gallo and OPV

Totally agree with Cliff's advice.

Anthony S. Fauci, MD

Director

National Institute of Allergy and Infectious Diseases

Building 31, Room 7A-03

31 Center Drive, MSC 2520

National Institutes of Health

Bethesda, MD 20892-2520

Phone: (b) (6)

FAX: (301) (b) (6)

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**From:** Lane, Cliff (NIH/NIAID) [E] (b) (6)

**Sent:** Sunday, May 3, 2020 1:22 PM

**To:** Collins, Francis (NIH/OD) [E] <(b) (6)>

**Cc:** Lowy, Douglas (NIH/NCI) [E] (b) (6); Fauci, Anthony (NIH/NIAID) [E] (b) (6);

Mascola, John (NIH/VRC) [E] (b) (6)

**Subject:** Re: Gallo and OPV

Francis,

I am not sure you need any sort of detailed response. I would just send a thank-you and indicate you will be sure those working on this at NIH are aware.

Cliff

On May 3, 2020, at 12:55 PM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Hi all,

I'm a bit at a loss to know how to respond to Bob Gallo. The aggressive manner in which he is promoting OPV causes me to worry he has lost objectivity about its promise. But is there any chance he has something here that could work?

Francis

COLL0000018272-2516996

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**From:** Gallo, Robert ( [REDACTED] )  
**Sent:** Sunday, May 31, 2020 12:07 PM  
**To:** Collins, Francis (NIH/OD) [E] < [REDACTED] > (b) (6)  
**Subject:** RE: Your query to Dr. Kadlec

Dear Francis,

It was a pleasure to hear from you, and yes, it has been a long time since we met or even spoke. Moons ago I was set to write to you after reading your wonderful book, but I ended up instead speaking with others about it. I should add at this point that I did not quickly respond to your email of a few days ago because I simply missed it.

It is true that I strongly suggest that OPV be quickly (already it is not quickly) brought forward for induction of a strong innate immune response to prevent or markedly reduce SARS-CoV-2 infection and/or severity until the field obtains a proven safe and efficacious vaccine producing a long lasting, adaptive immunity. OPV is very safe (notably for OPV 1 and 3 as bOPV which we will use and completely safe in a vaccinated population), simple, cheap, rather obvious, yet unique among the massive number of vaccines many (maybe most) of which are the same or at least if not exactly the same aiming at the same mechanism (targeting the spike and searching for the putative correlate of neutralizing Abs.).

OPV should work for a few months and possibly longer. Also it should be working multiple times so I think could cover more than a few months, giving us time for a proven vaccine of adaptive immunity, which might be very long lasting as is hoped.

In the main the WHO comments are correct. Of course we sought and have letters of support from them as well as from many others. Though they are again supportive in their notes to you, there is one item that surprises me. They add that there was no clinical efficacy results as yet. They know or certainly should know that there is plenty of clinical data for this concept with BCG, OPV, and live Measles vaccine. Needless to say this is what turned me on during our regular Global Virus Network (GVN) conference calls. (Incidentally GVN is an organization I have thought of bringing to your attention. I think you would find it impressive and useful). I would be happy to share with you the clinical observations with OPV if you wish.

I would like to take a small diversion, but I suspect you are aware of these things. My colleagues and I respect the WHO because of its representation and because we have colleagues/friends there as well. However, sometimes bureaucracy of a massive degree leads to inaction or even much worse— political expediency. I won't bother you with details of these unless you ask, but I had such experiences with HTLV-1 which we discovered in 1980 as the 1<sup>st</sup> human retrovirus and which cause not only the highest incidence of cancer (% of infections) of any virus and other fatal diseases as well but mainly in less developed countries (plus Japan) and again with HIV in 1984. Behavior was not beneficial. Perhaps it will be of relevance in the future because a few at WHO took a position to remove OPV (Sabin) in favor of IPV (Salk) in their polio eradication scheme. It was a huge failure. As my FDA collaborator, Konstantin Chumakov, says "Blessed be Bill Gates" because he saved OPV and saved the day and in so doing has produced a still better OPV.



There is indeed data also for BCG as well as live Measles though I know less of the latter. BCG is less available, requires injection, harder to make, not as safe, and we think unlikely to be as effective as OPV. Nonetheless, we favor its use too. The mechanisms will be similar.

You asked whether monkey trials are planned. For several reasons definitely not --though we are planning some monkey experiments, but not large enough for "clinical" conclusions. The main reasons are: 1) cost; 2) that billions not thousands or millions have received OPV safely and in our collective view (and we know the studies pretty well) protection has been clinically shown; 3) In a pandemic we wished to move quickly (so far we must say that has not been achieved). A typical monkey vaccine study will take time, but 4) in this case it would be a huge amount of lost time as monkeys require great doses of polio for infection and monkeys have to be trained to drink their orange juice. It would be hard to imagine that such studies would even give us useful information.

On a final digression Francis I have had 36 years of on/off experiences with glycosylated spike proteins—their analyses immunologically and especially regarding use in vaccines and developing neutralizing Abs. I believe it will be a mistake to put most eggs in that basket. The risks: shortened antibody half life; 2) protection NOT correlating with neutralizing Abs; 3) sometimes hazards from them. Admittedly, they might work, but I trust and hope that not everything is going in this bag. If you wish to discuss this again I will be available.

Finally, I had no idea you were into vaccines or SARS-2 nor any part of CoVID-19 disease, but I am very happy to learn this.

Thanks.

Bob Gallo

---

**From:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Sent:** Thursday, April 30, 2020 5:00 PM  
**To:** Gallo, Robert (b) (6)  
**Cc:** Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)>; Kadlec, Robert (OS/ASPR/IO) (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Shuy, Bryan (OS/ASPR/IO) <(b) (6)>; Johnson, Robert (OS/ASPR/BARDA) (b) (6)  
Mascola, John (NIH/VRC) [E] (b) (6); Lane, Cliff (NIH/NIAID) [E] (b) (6)  
**Subject:** Your query to Dr. Kadlec

**CAUTION:** This message originated from a non UMB, UMSOM, FPI, or UMMS email system. Whether the sender is known or not known, hover over any links before clicking and use caution opening attachments.

Dear Bob,

It's been quite a while since we've chatted. Bob Kadlec asked me to respond to your query about the possible use of OPV to activate innate immunity and provide COVID-19 protection. Has this been tested in a non-human primate model? I note the recommendation below that says a clinical trial is planned – can you tell me more about that?

As you can imagine, we are all flat out on the vaccine development pathway!



Francis

### **The use of oral polio vaccine (OPV) to prevent SARS-CoV2 (Polio Eradication Campaign)**

There is no evidence that oral poliovirus vaccine (OPV) protects people against infection with COVID-19 virus.

A clinical trial addressing this question is planned in the USA, and WHO will evaluate the evidence when it is available.

In the absence of evidence, WHO does not recommend OPV vaccination for the prevention of COVID-19. WHO continues to recommend OPV as part of essential immunization services to prevent poliomyelitis and as part of global polio eradication efforts.

There are experimental signals from various studies over the years that OPV has non-specific effects on the immune system. These effects have not been well characterized and their clinical relevance is unknown. Such non-specific effects may not be limited to OPV, as other live vaccines have also been associated with non-specific protective effects (such as BCG vaccine against tuberculosis). Nonlive vaccines in contrast do not seem to have the same effects.

The exact mechanism of non-specific protection induced by live vaccines needs to be elucidated further. Clinical studies could begin immediately because the vaccines in question are licensed and have an excellent safety record. Clinical trials involving off-label use of various drugs licensed for other indications are currently underway. The existing scientific rationale suggests that the same should be done for OPV and other live vaccines. A study is currently being discussed with various partners and vaccine manufacturers, including the US FDA, the outcomes of which will be carefully assessed to determine potential use in the context of the spread of SARS-CoV2 until the time when specific vaccines and antiviral therapies are ready.

---

**From:** Kadlec, Robert (OS/ASPR/IO) (b) (6)

**Sent:** Thursday, April 30, 2020 10:28 AM

**To:** Gallo, Robert (b) (6) Collins, Francis (NIH/OD) [E] (b) (6)

Tabak, Lawrence (NIH/OD) [E] (b) (6) >; Shuy, Bryan (OS/ASPR/IO)

< (b) (6)

**Subject:** Re: Response

Dr Gallo thank you for your note and I appreciate you reaching out to me. I have copied Dr Collins and Dr Tabak to consider the ACTIV forum they have created to bring industry academia and government to consider scientific base approaches That you have described. Dr Collins has organized a vaccine group and I assess could be the best and fastest place to discuss your concept. I am sure they will connect with you soonest

Best

Bob Kadlec.

Sent from my iPhone

COLL0000018272-2516996

On Apr 30, 2020, at 10:02 AM, Gallo, Robert (b) (6) > wrote:

Dear Dr. Kaldec,

I have not heard from you in over a week. You mentioned getting back to me in a day or two. Time is passing. I am asking you to look at OPV 1 plus 3 serotypes as a bivalent, completely safe vaccine with powerful stimulation of innate immunity lasting several weeks, which can be given a second or third time, and with a historical track record of preventing other infections from entirely different RNA viruses (such as protecting against influenza). Therefore, it should be really helpful for some months, and I think get us past a second wave of SARS-CoV-2, and help people return to work safely. I don't understand delays or apparent lack of interest. Who can possibly be against this? If you hear of hypothetical problems we can show you that these are false. Just ask the questions, and we can give you the evidence.

However, no answer from you suggests no interest and must quickly make alternative pathways. I am though quite surprised and fear you are receiving "fake news" if you will pardon the expression. Some have been against this who defend their old and failed position on polio eradication with their promotion of the use of the inactivated polio virus vaccine. Please note that in the US between 1962 and 1985 we received (safely) the oral polio (OPV). Moreover, if vaccinated already there has not been a single case of a complication and BILLIONS have received it. No it will not last long as innate immunity is short lived, but we strongly believe that we can break the back of the SARS-CoV-2 spread. Also note that this is what Bill Gates is doing now in India and much of the Eastern hemisphere.

There are countries outside the US wanting to move fast on this. We are waiting for your reply.

Robert Gallo  
Director, Institute of Human Virology,  
Professor of Medicine and Professor of Microbiology,  
UMB, School of Medicine, Baltimore,

And  
Co-founder and International Science Advisor of the Global Virus Network (GVN)



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**From:** Lowy, Douglas (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F1B7B8FE4739478BB17840C56902718A-LOWYD]  
**Sent:** 7/20/2020 9:02:35 PM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]  
**CC:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]  
**Subject:** Re: Gallo and OPV

Hi Francis,

As I mentioned at last week's ACTIV Executive Committee meeting, the vaccine working group listened to an invited presentation from Bob Gallo, who proposed two different clinical trials of oral poliovirus vaccine (OPV): a randomized controlled trial and/or a challenge study with a respiratory virus other than SARS-CoV-2, such as influenza or a standard coronavirus. In looking at the data for OPV, it appears to be observational. With BCG, by contrast, there are quite a few randomized controlled clinical trials and experimental studies that document its ability to reduce the risk of infection/disease attributable to other infectious agents. Currently, there are several RCT's being conducted in the US and other countries that are assessing the ability of BCG to reduce the risk of SARS-CoV-2 infection/disease.

The vaccine working group is planning to discuss this topic at its Wednesday meeting, and I am wondering what, if anything, you would like to do with the outcome of that discussion. Write back to Bob, or more than that?

Thanks,  
Doug

---

**From:** "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)>  
**Date:** Friday, July 3, 2020 at 12:07 PM  
**To:** "Lowy, Douglas (NIH/NCI) [E]" <(b) (6)> "Collins, Francis (NIH/OD) [E]" <(b) (6)> "Lane, Cliff (NIH/NIAID) [E]" <(b) (6)> "Mascola, John (NIH/VRC) [E]" <(b) (6)>  
**Cc:** "Wholley, David (FNIH) [T]" <(b) (6)>  
**Subject:** RE: Gallo and OPV

This issue will not go away and so perhaps it is best to have the ACTIV Vaccines WG take a look at this and make some sort of recommendation.

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**From:** Lowy, Douglas (NIH/NCI) [E] <(b) (6)>  
**Sent:** Friday, July 3, 2020 11:54 AM  
**To:** Collins, Francis (NIH/OD) [E] <(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Mascola, John (NIH/VRC) [E] <(b) (6)>  
**Cc:** Wholley, David (FNIH) [T] <(b) (6)>  
**Subject:** Re: Gallo and OPV

Hi Francis: The vaccine working group has not discussed this topic. Doug



---

**From:** "Collins, Francis (NIH/OD) [E]" (b) (6)  
**Date:** Friday, July 3, 2020 at 11:46 AM  
**To:** "Fauci, Anthony (NIH/NIAID) [E]" (b) (6); "Lane, Cliff (NIH/NIAID) [E]" (b) (6); "Lowy, Douglas (NIH/NCI) [E]" <(b) (6)> "Mascola, John (NIH/VRC) [E]" (b) (6)  
**Cc:** "Wholley, David (FNIH) [T]" <(b) (6)>  
**Subject:** RE: Gallo and OPV

Hi Tony, Cliff, Doug, and John (and looping in David)

Bob Gallo is back with a complaint that no one has followed up on the OPV idea. See attached. Was this discussed in the ACTIV Vaccines WG or in any other venue?

Tx, Francis

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**From:** Fauci, Anthony (NIH/NIAID) [E] (b) (6)  
**Sent:** Sunday, May 3, 2020 1:45 PM  
**To:** Lane, Cliff (NIH/NIAID) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Lowy, Douglas (NIH/NCI) [E] (b) (6); Mascola, John (NIH/VRC) [E] <(b) (6)>  
**Subject:** RE: Gallo and OPV

Totally agree with Cliff's advice.

Anthony S. Fauci, MD  
Director  
National Institute of Allergy and Infectious Diseases  
Building 31, Room 7A-03  
31 Center Drive, MSC 2520  
National Institutes of Health  
Bethesda, MD 20892-2520  
Phone: (b) (6)  
FAX: (301) (b) (6)  
E-mail: (b) (6)

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**From:** Lane, Cliff (NIH/NIAID) [E] (b) (6)  
**Sent:** Sunday, May 3, 2020 1:22 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Lowy, Douglas (NIH/NCI) [E] (b) (6); Fauci, Anthony (NIH/NIAID) [E] (b) (6); Mascola, John (NIH/VRC) [E] (b) (6)  
**Subject:** Re: Gallo and OPV

Francis,

I am not sure you need any sort of detailed response. I would just send a thank-you and indicate you will be sure those working on this at NIH are aware.

Cliff

On May 3, 2020, at 12:55 PM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Hi all,

I'm a bit at a loss to know how to respond to Bob Gallo. The aggressive manner in which he is promoting OPV causes me to worry he has lost objectivity about its promise. But is there any chance he has something here that could work?

Francis

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**From:** Gallo, Robert (b) (6)  
**Sent:** Sunday, May 3, 2020 12:07 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** RE: Your query to Dr. Kadlec

Dear Francis,

It was a pleasure to hear from you, and yes, it has been a long time since we met or even spoke. Moons ago I was set to write to you after reading your wonderful book, but I ended up instead speaking with others about it. I should add at this point that I did not quickly respond to your email of a few days ago because I simply missed it.

It is true that I strongly suggest that OPV be quickly (already it is not quickly) brought forward for induction of a strong innate immune response to prevent or markedly reduce SARS-CoV-2 infection and/or severity until the field obtains a proven safe and efficacious vaccine producing a long lasting, adaptive immunity. OPV is very safe (notably for OPV 1 and 3 as bOPV which we will use and completely safe in a vaccinated population), simple, cheap, rather obvious, yet unique among the massive number of vaccines many (maybe most) of which are the same or at least if not exactly the same aiming at the same mechanism (targeting the spike and searching for the putative correlate of neutralizing Abs.).

OPV should work for a few months and possibly longer. Also it should be working multiple times so I think could cover more than a few months, giving us time for a proven vaccine of adaptive immunity, which might be very long lasting as is hoped.

In the main the WHO comments are correct. Of course we sought and have letters of support from them as well as from many others. Though they are again supportive in their notes to you, there is one item that surprises me. They add that there was no clinical efficacy results as yet. They know or certainly should know that there is plenty of clinical data for this concept with BCG, OPV, and live Measles vaccine. Needless to say this is what turned me on during our regular Global Virus Network (GVN) conference calls. (Incidentally GVN is an organization I have thought of bringing to your attention. I think you would find it impressive and useful). I would be happy to share with you the clinical observations with OPV if you wish.

COLL0000015854-2516997



I would like to take a small diversion, but I suspect you are aware of these things. My colleagues and I respect the WHO because of its representation and because we have colleagues/friends there as well. However, sometimes bureaucracy of a massive degree leads to inaction or even much worse-- political expediency. I won't bother you with details of these unless you ask, but I had such experiences with HTLV-1 which we discovered in 1980 as the 1<sup>st</sup> human retrovirus and which cause not only the highest incidence of cancer (% of infections) of any virus and other fatal diseases as well but mainly in less developed countries (plus Japan) and again with HIV in 1984. Behavior was not beneficial. Perhaps it will be of relevance in the future because a few at WHO took a position to remove OPV (Sabin) in favor of IPV (Salk) in their polio eradication scheme. It was a huge failure. As my FDA collaborator, Konstantin Chumakov, says "Blessed be Bill Gates" because he saved OPV and saved the day and in so doing has produced a still better OPV.

There is indeed data also for BCG as well as live Measles though I know less of the latter. BCG is less available, requires injection, harder to make, not as safe, and we think unlikely to be as effective as OPV. Nonetheless, we favor its use too. The mechanisms will be similar.

You asked whether monkey trials are planned. For several reasons definitely not --though we are planning some monkey experiments, but not large enough for "clinical" conclusions. The main reasons are: 1) cost; 2) that billions not thousands or millions have received OPV safely and in our collective view (and we know the studies pretty well) protection has been clinically shown; 3) In a pandemic we wished to move quickly (so far we must say that has not been achieved). A typical monkey vaccine study will take time, but 4) in this case it would be a huge amount of lost time as monkeys require great doses of polio for infection and monkeys have to be trained to drink their orange juice. It would be hard to imagine that such studies would even give us useful information.

On a final digression Francis I have had 36 years of on/off experiences with glycosylated spike proteins--their analyses immunologically and especially regarding use in vaccines and developing neutralizing Abs. I believe it will be a mistake to put most eggs in that basket. The risks: shortened antibody half life; 2) protection NOT correlating with neutralizing Abs; 3) sometimes hazards from them. Admittedly, they might work, but I trust and hope that not everything is going in this bag. If you wish to discuss this again I will be available.

Finally, I had no idea you were into vaccines or SARS-2 nor any part of CoVID-19 disease, but I am very happy to learn this.

Thanks.

Bob Gallo

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**From:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Sent:** Thursday, April 30, 2020 5:00 PM  
**To:** Gallo, Robert (b) (6)  
**Cc:** Disbrow, Gary (OS/ASPR/BARDA) (b) (6); Kadlec, Robert (OS/ASPR/IO) (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Shuy, Bryan (OS/ASPR/IO) (b) (6); Johnson, Robert (OS/ASPR/BARDA) (b) (6); Mascola, John (NIH/VRC) [E] (b) (6); Lane, Cliff (NIH/NIAID) [E] (b) (6)  
**Subject:** Your query to Dr. Kadlec



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Dear Bob,

It's been quite a while since we've chatted. Bob Kadlec asked me to respond to your query about the possible use of OPV to activate innate immunity and provide COVID-19 protection. Has this been tested in a non-human primate model? I note the recommendation below that says a clinical trial is planned – can you tell me more about that?

As you can imagine, we are all flat out on the vaccine development pathway!

Francis

### **The use of oral polio vaccine (OPV) to prevent SARS-CoV2 (Polio Eradication Campaign)**

There is no evidence that oral poliovirus vaccine (OPV) protects people against infection with COVID-19 virus.

A clinical trial addressing this question is planned in the USA, and WHO will evaluate the evidence when it is available.

In the absence of evidence, WHO does not recommend OPV vaccination for the prevention of COVID-19. WHO continues to recommend OPV as part of essential immunization services to prevent poliomyelitis and as part of global polio eradication efforts.

There are experimental signals from various studies over the years that OPV has non-specific effects on the immune system. These effects have not been well characterized and their clinical relevance is unknown. Such non-specific effects may not be limited to OPV, as other live vaccines have also been associated with non-specific protective effects (such as BCG vaccine against tuberculosis). Nonlive vaccines in contrast do not seem to have the same effects.

The exact mechanism of non-specific protection induced by live vaccines needs to be elucidated further. Clinical studies could begin immediately because the vaccines in question are licensed and have an excellent safety record. Clinical trials involving off-label use of various drugs licensed for other indications are currently underway. The existing scientific rationale suggests that the same should be done for OPV and other live vaccines. A study is currently being discussed with various partners and vaccine manufacturers, including the US FDA, the outcomes of which will be carefully assessed to determine potential use in the context of the spread of SARS-CoV2 until the time when specific vaccines and antiviral therapies are ready.

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**From:** Kadlec, Robert (OS/ASPR/IO) (b) (6)  
**Sent:** Thursday, April 30, 2020 10:28 AM  
**To:** Gallo, Robert (b) (6); Collins, Francis (NIH/OD) [E] (b) (6);  
Tabak, Lawrence (NIH/OD) [E] <(b) (6)>; Shuy, Bryan (OS/ASPR/IO)  
(b) (6)  
**Subject:** Re: Response

COLL0000015854-2516997

Dr Gallo thank you for your note and I appreciate you reaching out to me. I have copied Dr Collins and Dr Tabak to consider the ACTIV forum they have created to bring industry academia and government to consider scientific base approaches That you have described. Dr Collins has organized a vaccine group and I assess could be the best and fastest place to discuss your concept. I am sure they will connect with you soonest

Best

Bob Kadlec.

Sent from my iPhone

On Apr 30, 2020, at 10:02 AM, Gallo, Robert < (b) (6) > wrote:

Dear Dr. Kaldec,

I have not heard from you in over a week. You mentioned getting back to me in a day or two. Time is passing. I am asking you to look at OPV 1 plus 3 serotypes as a bivalent, completely safe vaccine with powerful stimulation of innate immunity lasting several weeks , which can be given a second or third time, and with a historical track record of preventing other infections from entirely different RNA viruses (such as protecting against influenza). Therefore, it should be really helpful for some months, and I think get us past a second wave of SARS-CoV-2, and help people return to work safely. I don't understand delays or apparent lack of interest. Who can possibly be against this? If you hear of hypothetical problems we can show you that these are false. Just ask the questions, and we can give you the evidence.

However, no answer from you suggests no interest and must quickly make alternative pathways. I am though quite surprised and fear you are receiving "fake news" if you will pardon the expression. Some have been against this who defend their old and failed position on polio eradication with their promotion of the use of the inactivated polio virus vaccine. Please note that in the US between 1962 and 1985 we received (safely) the oral polio (OPV). Moreover, if vaccinated already there has not been a single case of a complication and BILLIONS have received it. No it will not last long as innate immunity is short lived, but we strongly believe that we can break the back of the SARS-CoVID-2 spread. Also note that this is what Bill Gates is doing now in India and much of the Eastern hemisphere.

There are countries outside the US wanting to move fast on this. We are waiting for your reply.

Robert Gallo  
Director, Institute of Human Virology,  
Professor of Medicine and Professor of Microbiology,  
UMB, School of Medicine, Baltimore,

And

Co-founder and International Science Advisor of the Global Virus Network (GVN)



**From:** Pangalos, Mene [ (b) (6) ]  
**Sent:** 6/5/2020 10:55:10 AM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]  
**CC:** Esser, Mark [ (b) (6) ] Villafana, Tonya [ (b) (6) ]  
**Subject:** RE: combinatorics and monoclonal Abs - Data Shared In Confidence

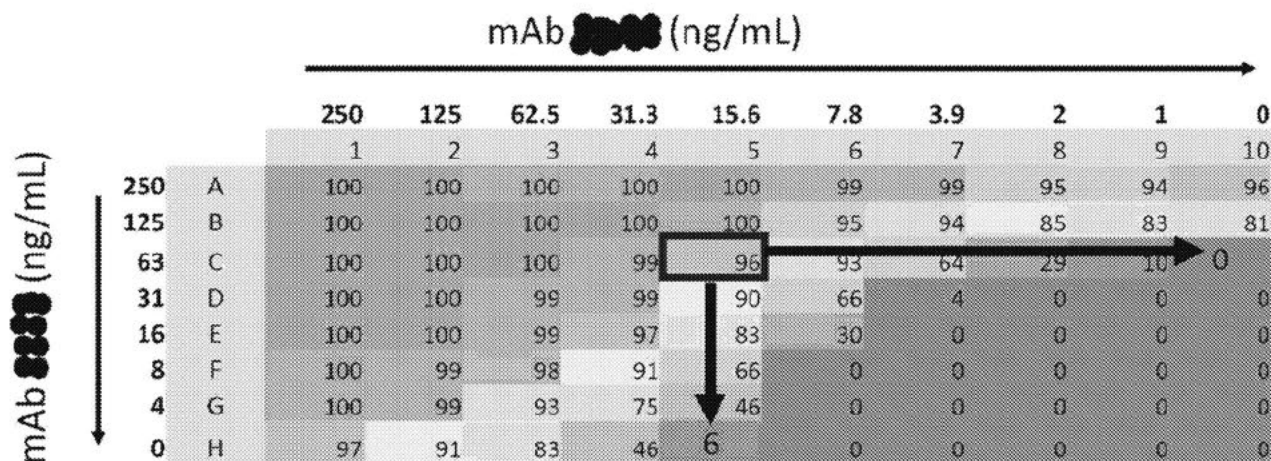
Francis,

We do these assays ourselves and with collaborators... they are often done in oncology as I am sure you know. This is data from two of our mAbs that demonstrated what we are looking for.

Please do not share this data set as is yet to be published and I am sharing in confidence but hopefully gives you a sense of what we do and what we hope to observe. Our cocktail moving forward will take the two mAbs with the best synergistic effect in neut assays into the clinic (which we have in fact already selected).

These sorts of assays could be used to test a variety of antibodies from different sources to find combinations that work and will be important if resistance emerges.

Mene



**Sir Menelas N Pangalos PhD FRSB FMedSci**  
EVP & President BioPharmaceuticals R&D  
AstraZeneca, Melbourn Science Park,  
Cambridge Road, Royston, Herts SG8 6EE

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**From:** Collins, Francis (NIH/OD) [E] < (b) (6) >

**Sent:** 05 June 2020 02:26

**To:** Pangalos, Mene < (b) (6) >

**Cc:** Wholley, David (FNIH) [T] < (b) (6)>

**Subject:** combinatorics and monoclonal Abs

Hi Mene,

I think I heard you say something during the ACTIV call yesterday about ways to optimize the choice of mAbs that would be synergistic. For the upcoming inpatient and outpatient trials of mAbs against SARS-CoV-2, it would be great to have available a preclinical in vitro assay that could predict that kind of synergy in vivo. Do you have an approach that you or someone on your staff would be willing to tell me about?

Best, Francis

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**From:** Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]  
**on behalf of** Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]  
**Sent:** 11/23/2020 4:17:50 PM  
**To:** Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Bancel, Stephane [ (b) (6) Carter, Kara [ (b) (6) Cavaleri, Marco [ (b) (6) Cihlar, Tomas [ (b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [ (b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Victoria Davey [ (b) (6) Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Dolsten, Mikael [ (b) (6) Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Erck, Stan [ (b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [ (b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [ (b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John [ (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [ (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Pandya, Hitesh [ (b) (6) Pangalos, Mene [ (b) (6) Pao, William [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Paul, Steve [ (b) (6) Perlmutter, Roger [ (b) (6) Plenge, Robert [ (b) (6) Plump, Andy [ (b) (6) Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Reed, John [ (b) (6) Reese, David [ (b) (6) Rouse, Doris [ (b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [ (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [ (b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael [ (b) (6) Tsai, John [ (b) (6) Vessey, Rupert [ (b) (6) ]; Virgin,



Skip [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [ (b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John

CC: [ (b) (6) Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Carluccio, Dana [ (b) (6) Castillejos, Carlos [ (b) (6) FNIH Central Account [ (b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Gorman, Greta (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mendelson, Jesse [ (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; btolman [/o=ExchangeLabs/ou=Exchange Administrative

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Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Tountas, Karen (FNIH) [T]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan  
(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

**Subject:** Notes from Thursday's ACTIV Leadership Team Meeting

**Attachments:** 2020-11-19\_ACTIV\_Leadership\_Team\_Meeting\_Summary\_v3.docx

Dear Leadership Team members and meeting attendees:

Please see the notes from our teleconference this past Thursday, November 19. Please let me know any additional comments, questions, or suggestions regarding these notes or the action items.

Thank you again for all your support of and contributions to ACTIV.

Regards,

David

David Wholley  
Senior Vice-President, Research Partnerships  
Foundation for the National Institutes of Health

(b) (6)

[fnih.org](http://fnih.org)

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

*In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.*



**From:** Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]  
**Sent:** 5/18/2020 7:21:29 PM  
**To:** (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; (b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell (b) (6) [ (b) (6) (b) (6) Cavalieri Marco [ (b) (6) (b) (6) (b) (6) Greg Glenn [ (b) (6) (b) (6) Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; hotez@bcm.edu; (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) [ (b) (6) Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbd9cc56fde4598a57b423d484dcf9f-offit.email]; (b) (6) Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccba4e3caaf5eb5d3586b1cc-Jonathan.Se]; (b) (6) Tal Zaks [ (b) (6)  
**CC:** Tolman, Brett [ (b) (6) Jessica. (b) (6) Hopps, Markay [ (b) (6) Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; (b) (6) Jeneffer Haynes (b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; (b) (6) Isabel Ramsey [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Hughes, Eric [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John



(b) (6) Paul Gillard [ (b) (6) Hamilton, Holli (OS/ASPR/BARDA)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa4222d0576cc-Holli.Hamil]; Modjarrad, Kayvon CIV  
USARMY MEDCOM WRAIR (USA) [ (b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange  
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som];  
Schrage, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R.  
(CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Thornburg, Natalie  
(CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Gonzalez, Nina  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];  
Wachtel, Jonathan [ (b) (6) Stratton, Benjamin [ (b) (6) Anderson, Margaret  
 [ (b) (6) (b) (6) ; Bethany Stokes  
 (b) (6)

**Subject:** ACTIV Vaccines Working Group meeting

**Location:** Webex: <https://nih.webex.com/>, (b) (6)

**Start:** 5/28/2020 6:00:00 PM

**End:** 5/28/2020 7:00:00 PM

**Show Time As:** Tentative

**Required Attendees:** (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann; Beth Bell  
(b) (6) (b) (6) Cavaleri Marco; (b) (6)  
(b) (6) (b) (6) Greg Glenn; (b) (6) Haynes,  
Barton; (b) (6) (b) (6) .ch; Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];  
Messonnier, Nancy (CDC/DDID/NCIRD/OD); Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA); Offit, Paul;  
(b) (6) Seals, Jonathan (OS/ASPR/BARDA); (b) (6) Tal Zaks  
**Optional Attendees:** Tolman, Brett; (b) (6) Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen  
(NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6)  
(b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker,  
Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Wholley, David (FNIH) [T];  
Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James,  
Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS)  
[E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV  
USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Schrage, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R.  
(CDC/DDID/NCIRD/DBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton,  
Benjamin; Anderson, Margaret; rose. (b) (6) (b) (6) Bethany Stokes

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---

**From:** Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]  
**Sent:** 4/16/2020 12:10:13 PM  
**To:** Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]  
**CC:** Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]  
**Subject:** RE: PLEASE READ: Draft Email to Collect Communication Contact Information  
**Attachments:** Master list for ACTIV.xlsx

I pulled the names from the attached that you sent earlier in the week. There isn't a Takeda contact on this list. Would you send it to me?

---

**From:** Parker, Ashley (NIH/OD) [E] <(b) (6)>  
**Sent:** Thursday, April 16, 2020 8:03 AM  
**To:** Myles, Renate (NIH/OD) [E] <(b) (6)>  
**Cc:** Wolinetz, Carrie (NIH/OD) [E] <(b) (6)>  
**Subject:** RE: PLEASE READ: Draft Email to Collect Communication Contact Information

Good morning Renate,

Our rep at Takeda, Andy Plump is included on the master list. I am confirming with Francis that he used our master list for his email that went out last night – **I should be able to confirm this for you this morning.**

I hope you are staying safe and healthy; maybe even getting some rest in between the constant COVID activities.

Thanks,  
Ashley

---

**From:** Myles, Renate (NIH/OD) [E] <(b) (6)>  
**Sent:** Thursday, April 16, 2020 7:14 AM  
**To:** Parker, Ashley (NIH/OD) [E] <(b) (6)>  
**Cc:** Wolinetz, Carrie (NIH/OD) [E] <(b) (6)>  
**Subject:** FW: PLEASE READ: Draft Email to Collect Communication Contact Information  
**Importance:** High

Hi Ashley:

I'm not sure if Francis added a Takeda contact to his email. I could not find one on the master contact list. I have not heard from their organizations yet. Would you let me know if you provided that to him last night or if they are missing from this email? Need to send it to this group this morning.

Thanks,  
Renate

---

**From:** Myles, Renate (NIH/OD) [E]  
**Sent:** Wednesday, April 15, 2020 9:11 PM  
**To:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Cc:** Wood, Gretchen (NIH/OD) [E] <(b) (6)>; McManus, Ayanna (NIH/OD) [E] <(b) (6)>; Burklow, John (NIH/OD) [E] <(b) (6)>; >; Parker, Ashley (NIH/OD) [E] <(b) (6)>



**Subject:** PLEASE READ: Draft Email to Collect Communication Contact Information

**Importance:** High

Hi Francis:

We need to collect the communication contacts from the partner organizations so we can share the release with them for review. Below is 1) a draft email for you to send to the company participants, 2) the contacts for the companies we list in the release except for Takeda (I could not find a Takeda contact on the master list; hoping Ashley can provide); 3) those who should be copied (feel free to add others).

Dear ACTIV colleagues:

As I mentioned earlier today, we would like to announce the plans for a public-private partnership as expeditiously as possible. Please provide the name of the most appropriate communication contact from your company so that we may share a draft of the embargoed press release for your review. Please send the contact information to Renate Myles at

(b) (6)

and Abbey Meltzer

(b) (6)

this evening, if possible.

BCC:

(b) (6)

CC:

(b) (6)

Thanks,  
Renate

**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 5/7/2020 8:56:22 PM  
**To:** Eric Hughes [ (b) (6) ]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [ (b) (6) ]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [ (b) (6) ]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [ (b) (6) ]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [ (b) (6) ]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [ (b) (6) ]; Keith Gottesdiener [ (b) (6) ]; Elliott Levy [ (b) (6) ]; Wung, Peter /US [ (b) (6) ]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [ (b) (6) ]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]  
**CC:** Elizabeth Kim [ (b) (6) ]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [ (b) (6) ]; Salathin, Carla [ (b) (6) ]; (b) (6) [ (b) (6) ]; (b) (6) [ (b) (6) ]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [ (b) (6) ]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]  
**Subject:** ACTIV TX-Clinical Agent Prioritization Subgroup #9  
**Location:** [https://fnih.zoom. \(b\) \(6\)](https://fnih.zoom. (b) (6))  
**Start:** 5/12/2020 5:00:00 PM  
**End:** 5/12/2020 6:00:00 PM  
**Show Time As:** Tentative

**Required Attendees:** Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]  
**Optional Attendees:** Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; (b) (6) [ (b) (6) ]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] (b) (6)

Stacey Adam is inviting you to a scheduled Zoom meeting.

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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 5/20/2020 6:20:54 PM  
**To:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier  
(b) (6) Eric Hughes [ (b) (6) LaVange, Lisa M [ (b) (6)  
Sandeep Menon [ (b) (6) Proschan, Michael (NIH/NIAID) [E] [ (b) (6)  
Read, Sarah (NIH/NIAID) [E] (b) (6) ]; Price, Dionne (FDA/CDER) [D (b) (6) Rubin,  
Daniel B. (FDA/CDER) (b) (6) Farley, John (FDA/CDER) (b) (6) Karen Lynn  
Price [ (b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) (b) (6) Eron, Joe  
(b) (6) Javan, Arzhang (NIH/NIAID) [E] [ (b) (6) Roa, Jhoanna [ (b) (6)  
(b) (6) Kim, Peter (NIH/NIAID) [E] [ (b) (6) Jonathan Li [ (b) (6) Marks,  
Gilbert (OS/ASPR/BARDA) (CTR) [ (b) (6) Kozak, Marina (OS/ASPR/BARDA)  
[ (b) (6)  
**CC:** Demarcus [ (b) (6) Tountas, Karen (FNIH) [T] [ (b) (6) Wachtel, Jonathan  
(b) (6) Elizabeth Kim [ (b) (6) Parker, Ashley (NIH/OD) [E]  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa  
[ (b) (6) Eron, Joseph J Jr (b) (6) Smith, David  
[ (b) (6) Paul Klekotka [ (b) (6) Ajay Nirula [ (b) (6) Elsaid,  
Olivia [ (b) (6) Robert Jan Benschop (b) (6) ; Lei Shen [ (b) (6)  
**Subject:** Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3  
**Attachments:** 5401 Protocol Synopsis 051920v3.docx  
**Location:** <https://fnih.zoom.us/>, (b) (6)  
**Start:** 5/20/2020 10:00:00 PM  
**End:** 5/20/2020 11:00:00 PM  
**Show Time As:** Tentative

**Required Attendees:** Judy Currier; Eric Hughes; LaVange, Lisa M; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; (b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; (b) (6) Kim, Peter (NIH/NIAID) [E]; Jonathan Li; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)  
**Optional Attendees:** Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen

Dear mAb Outpatient WT,

It seems like we can still get quorum, so I think we should proceed with who we have.

Thanks,

Stacey

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Password: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

**From:** Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]  
**Sent:** 11/12/2020 5:10:25 PM  
**To:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] (b) (6); Carter, Kara [ (b) (6) Cavaleri, Marco [ (b) (6) Cihlar, Tomas [ (b) (6) ; Collins, Francis (NIH/OD) [E] [ (b) (6) Corey, Larry [ (b) (6) Culp, Michelle (NIH/OD) [E] [ (b) (6) Disbrow, Gary (OS/ASPR/BARDA) [ (b) (6) Dolsten, Mikael [ (b) (6) Erbeling, Emily (NIH/NIAID) [E] [ (b) (6) ]; Erck, Stan [ (b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] (b) (6) Hudson, Thomas [ (b) (6) James, Stephanie (FNIH) [T] [ (b) (6) Johnson, Robert (OS/ASPR/BARDA) [ (b) (6) Kramer, Lynn [ (b) (6) Lane, Cliff (NIH/NIAID) [E] [ (b) (6) Marks, Peter (FDA/CBER) (b) (6) Marston, Hilary (NIH/NIAID) [E] [hila (b) (6) Mascola, John (NIH/VRC) [E] (b) (6) Meeker, David [ (b) (6) Menetski, Joseph (FNIH) [T] (b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) [ (b) (6) Pandya, Hitesh [hi (b) (6) Parker, Ashley (NIH/OD) [E] [ (b) (6) Perlmutter, Roger [ (b) (6) Plenge, Robert [ (b) (6) Rachel Ramoni [ (b) (6) Rasi, Guido (b) (6); Rouse, Doris (b) (6); Santos, Michael (FNIH) [T] [ (b) (6) Skovronsky, Daniel [ (b) (6) Stein, Peter (FDA/CDER) [ (b) (6) Stoffels, Paul [ (b) (6) .com]; Tabak, Lawrence (NIH/OD) [E] [ (b) (6) Talley, Michael [ (b) (6) Vessey, Rupert [ (b) (6) Wholley, David (FNIH) [T] [ (b) (6) Woodcock, Janet (FDA/CDER) [ (b) (6) Young, John [ (b) (6) Colvis, Christine (NIH/NCATS) [E] [christ (b) (6) Desrosiers, Betsy [el (b) (6) Eric Hughes [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [ (b) (6) Lowy, Douglas (NCI) [ (b) (6) Read, Sarah (NIH/NIAID) [E] [ (b) (6) Victoria Davey [ (b) (6) (b) (6) Villafana, Tonya [tonya.vil (b) (6) Bancel, Stephane [ (b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Lepore, John (b) (6) Pangalos, Mene [ (b) (6) Pao, William [ (b) (6) Paul, Steve [ (b) (6) Plump, Andy [ (b) (6) Reed, Johr (b) (6); Reese, David [ (b) (6) Tsai, John [john. (b) (6) Anderson, James (NIH/OD) [E] [ (b) (6) ]; Burklow, John (NIH/OD) [E] [ (b) (6) Carluccio, Dana [ (b) (6) Castillejos, Carlos [ (b) (6) FNIH Central Account [fn (b) (6) Hallett, Adrienne (NIH/OD) [E] [adrienne.hallett@nih.gov]; Myles, Renate (NIH/OD) [E] [ (b) (6) .gov]; Wolinetz, Carrie (NIH/OD) [E] [ (b) (6) Adam, Stacey (FNIH) [T] [ (b) (6) Margaret Anderson [ (b) (6) Appell, Evan [ (b) (6) Chen, Helen Q. [ (b) (6) Connelly, Sarah [ (b) (6) Gonzalez, Nina [ningonza (b) (6) Hawk, Harrison [ (b) (6) ]; Mendelson, Jesse [ (b) (6) m]; asorosa [ (b) (6) Stratton, Benjamin [ (b) (6) btolman [ (b) (6) Tountas, Karen (FNIH) [T] (b) (6); Wachtel, Jonathan [ (b) (6) Gorman, Greta (FNIH) [T] [ (b) (6) Meltzer, Abbey (FNIH) [T] (b) (6); Austin, Sarah (NIH/NIAID) [E] [ (b) (6) Barasch, Kimberly (NIH/NIAID) [C] [kimberly.ba (b) (6) Bell, Julie (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [ (b) (6) Carver, Trea (NIH) [C] [ (b) (6) Caulfied, Anita [ (b) (6) Coan, Amanda [ (b) (6) ]; Conrad, Patricia (NIH/NIAID) [E] [conradpa@niaid.nih.gov]; Dimishkov, Roxanne (NIH/NHLBI) [C] [ (b) (6) ]; Edl, Susan [susan.ed (b) (6) Fuhrer, Nicole [ (b) (6) Giorgi, Sara [ (b) (6) Hoffstetter, Renata (FNIH) [T] [ (b) (6) Iberdemaj, Vaide [ (b) (6) Jenkins, Christine S. [ (b) (6) Lagos, Enrique (NIH/NCATS) [E] [ (b) (6) ]; Lever, Susan [susan. (b) (6) McManus, Ayanna (NIH/OD) [E] [ (b) (6) Minnich, Beth [ (b) (6) Perala, Mie [mie.pera (b) (6) Protasiewicz, Ann [ann. (b) (6) Riccobene, Kim [ (b) (6) Riggins, Mary [ (b) (6) Ripley, Nadege [ (b) (6) Schuster, Donna [ (b) (6) Sepulveda, Dorina (FNIH) [T] [ (b) (6) Simon, Dina (NIH/OD) [C]



[ (b) (6) ] Suhana, Tina (NIH/VRC) [E] [ (b) (6) ]; Thomas, Ashley (FDA/CDER)  
[ (b) (6) ]; Wood, Gretchen (NIH/OD) [E] [ (b) (6) ]; Hughes, Karen (NIH/OD) [E]  
[karen. (b) (6) ]; Tajalli, Ada (NIH/OD) [E] [ (b) (6) ]; Togashi, Mieko (NIH/NCI) [E]  
[ (b) (6) ]; Underwood, Nancy [ (b) (6) ] Zottoli, Jessica  
[ (b) (6) ] Vessey, Rupert [ (b) (6) ] Regan, Donna M  
[ (b) (6) ] Grant, Sarah [ (b) (6) ] Plenge, Robert [ (b) (6) ]  
Lowy, Douglas (NIH/NCI) [E] [ (b) (6) ] Nasr, Hana [ (b) (6) ] Hoban, Michelle  
[ (b) (6) ]

**Subject:** ACTIV Leadership Team Meeting #11

**Location:** <https://fnih.zoom.us/> (b) (6)

**Start:** 12/16/2020 3:00:00 PM

**End:** 12/16/2020 4:30:00 PM

**Show Time As:** Busy

**Required Attendees:** Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Victoria Davey; (b) (6) Villafana, Tonya

**Optional Attendees:** Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfied, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggan, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Hughes, Karen (NIH/OD) [E]; Tajalli, Ada (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Vessey, Rupert; Regan, Donna M; Grant, Sarah; Plenge, Robert; Lowy, Douglas (NIH/NCI) [E]; Nasr, Hana

Extending the call by 30 minutes per discussion at Nov. 19 Leadership Team call

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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**From:** Proschan, Michael (NIH/NIAID) [E] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=7B45059209B4468BB4BA02B0DFBBB3E4-PROSCHAM]  
**Sent:** 4/30/2020 5:18:10 PM  
**To:** LaVange, Lisa M [ (b) (6) 'Levy, Elliott' (b) (6) ]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan\_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fda]; Mark Eisner [ (b) (6) Keith Gottesdiener [ (b) (6) Eric Hughes [ (b) (6) Sandeep Menon [ (b) (6) Amanda Peppercorn [ (b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [ (b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f29042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [ (b) (6)  
**CC:** Mary Biggs [ (b) (6) DeMarcus, Forrest [ (b) (6) Macone, Erin [ (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) Elizabeth Kim [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wung, Peter /US [ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Stratton, Benjamin [ (b) (6)  
**Subject:** RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

I believe that the intent is to for a rate recovery ratio of 1.25 in ACTT2 (baricitinib+remdesivir versus remdesivir), although it has not been finalized. Going for less than 1.25 really drives up the sample size.

Mike.

---

**From:** LaVange, Lisa M < (b) (6) >  
**Sent:** Thursday, April 30, 2020 11:19 AM  
**To:** 'Levy, Elliott' < (b) (6) > Adam, Stacey (FNIH) [T] < (b) (6) > Bozzette, Sam (NIH/NCATS) [E] < (b) (6) > Butterson, Joan < (b) (6) > Collins, Sylva (FDA/CDER)



<Sylva.Collins@fda.hhs.gov>; Judy Currier <(b) (6)> De Claro, R. Angelo (FDA/CDER)  
<(b) (6)> Mark Eisner <(b) (6)> Keith Gottesdiener  
<(b) (6)> Eric Hughes <(b) (6)> Sandeep Menon  
<(b) (6)> Amanda Peppercorn <(b) (6)> Proschan, Michael  
(NIH/NIAID) [E] <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Amanda Peppercorn  
<(b) (6)> Price, Dionne (FDA/CDER) <(b) (6)> Rubin, Daniel B.  
(FDA/CDER) <daniel.(b) (6)> Shen, Yuan Li (FDA/CDER) <(b) (6)> Farley, John  
(FDA/CDER) <(b) (6)> Goff, David (NIH/NHLBI) [E] <(b) (6)> Vincent, Michael  
<Michael.(b) (6)>  
**Cc:** Mary Biggs <(b) (6)> DeMarcus, Forrest <(b) (6)> Macone, Erin  
<(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> Wachtel, Jonathan <(b) (6)>  
Elizabeth Kim <(b) (6)> Parker, Ashley (NIH/OD) [E] <ashley.pa (b) (6)> Butcher, Tina  
<(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T]  
<(b) (6)> Wung, Peter /US <(b) (6)> Qashu, Felicia (NIH/OD) [E]  
<felicia.(b) (6)> Stratton, Benjamin <(b) (6)>  
**Subject:** RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

My concern with the target RRR is whether another agent will be superior to an effective drug to the same extent as remdesivir was to a less effective SoC. Might we need to lower the RRR beyond 1.25?  
And these emails highlight why it is probably better to discuss as a group—sorry!  
Talk to everyone soon,  
Lisa

---

**From:** Levy, Elliott <(b) (6)>  
**Sent:** Thursday, April 30, 2020 10:24 AM  
**To:** LaVange, Lisa M <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Bozzette, Sam (NIH/NCATS) [E] <(b) (6)> Butters, Joan <(b) (6)> Collins, Sylva (FDA/CDER) <(b) (6)> Judy Currier <(b) (6)> >; De Claro, R. Angelo (FDA/CDER) <(b) (6)> Mark Eisner <(b) (6)> Keith Gottesdiener <(b) (6)> Eric Hughes <(b) (6)> Sandeep Menon <(b) (6)> Amanda Peppercorn <(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Amanda Peppercorn <(b) (6)> Price, Dionne (FDA/CDER) <(b) (6)> Rubin, Daniel B. (FDA/CDER) <(b) (6)> Shen, Yuan Li (FDA/CDER) <(b) (6)> >; Farley, John (FDA/CDER) <(b) (6)> ; Goff, David (NIH/NHLBI) [E] <(b) (6)> Vincent, Michael <(b) (6)>  
**Cc:** Mary Biggs <(b) (6)> >; DeMarcus, Forrest <(b) (6)> >; Macone, Erin <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> ; Wachtel, Jonathan <(b) (6)> Elizabeth Kim <(b) (6)> ; Parker, Ashley (NIH/OD) [E] <(b) (6)> >; Butcher, Tina <(b) (6)> ; Wholley, David (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)> ; Wung, Peter /US <(b) (6)> >; Qashu, Felicia (NIH/OD) [E] <(b) (6)> Stratton, Benjamin <(b) (6)>  
**Subject:** RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

I agree that remdesivir will need to become background therapy in all treatment arms. This gives us to opportunity to test regimens which target both the virus and the host, which is exciting.

With regard to the target RRR, in my view the emerging data confirm the need to power for 1.25, rather than something larger:

-Remdesivir (a rationally designed therapy) exhibited an effect of 1.31 in ACCT1 on TTR, and a somewhat smaller effect (1.23) in the terminated Chinese trial. These are our best estimates for what a rationally designed therapy can do.

-In ACCT1, an effect of 1.31 was associated with a reduction in duration of hospital stay by 4 days, which would be meaningful from a health care system perspective.

-I would not expect other therapies we test to exhibit a larger effect than remdesivir. They were not designed to address the pathophysiology of COVID-19, about which we know little, and their benefit might be partially attenuated when used in combination with another active agent.

-A smaller effect for the experimental therapy would still be meaningful, if one could infer the combination of experimental therapy + remdesivir had an effect of 1.5 or more.

Elliott

---

**From:** LaVange, Lisa M (b) (6)  
**Sent:** Thursday, April 30, 2020 6:50 AM  
**To:** Adam, Stacey (FNIH) [T] (b) (6); Bozzette, Sam (NIH/NCATS) [E] <(b) (6)>; Butterson, Joan (b) (6); Collins, Sylva (FDA/CDER) (b) (6); Judy Currier (b) (6); De Claro, R. Angelo (FDA/CDER) (b) (6); Mark Eisner (b) (6); Keith Gottesdiener (b) (6); Eric Hughes (b) (6); Levy, Elliott (b) (6); Sandeep Menon (b) (6); Amanda Peppercorn (b) (6); Proschan, Michael (NIH/NIAID) [E] (b) (6); Read, Sarah (NIH/NIAID) [E] (b) (6); Amanda Peppercorn (b) (6); Price, Dionne (FDA/CDER) (b) (6); Rubin, Daniel B. (FDA/CDER) (b) (6); Shen, Yuan Li (FDA/CDER) (b) (6); Farley, John (FDA/CDER) (b) (6); Goff, David (NIH/NHLBI) [E] (b) (6); Vincent, Michael (b) (6)  
**Cc:** Mary Biggs (b) (6); DeMarcus, Forrest (b) (6); Macone, Erin (b) (6); Tountas, Karen (FNIH) [T] (b) (6); Wachtel, Jonathan (b) (6); Elizabeth Kim <elkim@fda.gov> (b) (6); Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov> (b) (6); Butcher, Tina (b) (6); Wholley, David (FNIH) [T] (b) (6); Melencio, Cheryl (FNIH) [T] (b) (6); Wung, Peter /US (b) (6); Qashu, Felicia (NIH/OD) [E] (b) (6); Stratton, Benjamin (b) (6)  
**Subject:** [External] Re: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Agree, thanks for raising this, Sam. There are other implications as well. We may need to revisit the meds we will allow as background therapy, now that we have a true standard of care consistent across all sites. And is the target RRR we want to be powered to detect (1.25) the appropriate target relative to Remdesivir?

Looking forward to talking further later today.

Lisa

---

**From:** Adam, Stacey (FNIH) [T] <stacey.adam@fda.gov> (b) (6)  
**Sent:** Thursday, April 30, 2020 9:44 AM  
**To:** Bozzette, Sam (NIH/NCATS) [E] (b) (6); Butterson, Joan (b) (6); Collins, Sylva (FDA/CDER) <collins.sylva@fda.gov> (b) (6); Judy Currier <judy.currier@fda.gov> (b) (6); De Claro, R. Angelo (FDA/CDER) (b) (6); Mark Eisner (b) (6); Keith Gottesdiener (b) (6); Eric Hughes (b) (6); LaVange, Lisa M (b) (6); Elliott Levy (b) (6); Sandeep Menon (b) (6); Amanda Peppercorn (b) (6); Proschan, Michael (NIH/NIAID) [E] (b) (6); Read, Sarah (NIH/NIAID) [E] (b) (6); Amanda Peppercorn (b) (6); Price, Dionne (FDA/CDER) (b) (6); Rubin, Daniel B. (FDA/CDER) (b) (6); Shen, Yuan Li (FDA/CDER) (b) (6); Farley, John (FDA/CDER) (b) (6); Goff, David (NIH/NHLBI) (b) (6)



[E] < (b) (6) ; Vincent, Michael < (b) (6)  
**Cc:** Mary Biggs (b) (6) >; DeMarcus, Forrest (b) (6) : Macone, Erin  
(b) (6) >; Tountas, Karen (FNIH) [T] < (b) (6) : Wachtel, Jonathan (b) (6)  
Elizabeth Kim (b) (6) >; Parker, Ashley (NIH/OD) [E] ( ) Butcher, Tina  
(b) (6) >; Wholley, David (FNIH) [T] (b) (6) >; Melencio, Cheryl (FNIH) [T]  
(b) (6) ; Wung, Peter /US (b) (6) >; Qashu, Felicia (NIH/OD) [E]  
(b) (6) >; Stratton, Benjamin (b) (6)

**Subject:** RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Hi Sam,

I think you are correct and we can discuss more today and tomorrow. I am currently trying to figure out what the outreach procedure should be, but I agree it likely needs to sooner rather than later.

Thanks,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnerships  
Direct: (b) (6) | Mobile: (b) (6)

---

**From:** Bozzette, Sam (NIH/NCATS) [E] (b) (6)  
**Sent:** Thursday, April 30, 2020 9:19 AM  
**To:** Adam, Stacey (FNIH) [T] < (b) (6) : Butterton, Joan (b) (6) >; Collins, Sylva  
(FDA/CDER) (b) (6) >; Judy Currier (b) (6) >; De Claro, R. Angelo (FDA/CDER)  
(b) (6) Mark Eisner (b) (6) >; Keith Gottesdiener  
(b) (6) Eric Hughes (b) (6) >; LaVange, Lisa M (b) (6)  
Elliott Levy <el (b) (6) : Sandeep Menon (b) (6) ; Amanda Peppercorn  
(b) (6) >; Proschan, Michael (NIH/NIAID) [E] (b) (6) Read, Sarah  
(NIH/NIAID) [E] (b) (6) Amanda Peppercorn (b) (6) >; Price, Dionne  
(FDA/CDER) < (b) (6) : Rubin, Daniel B. (FDA/CDER) < (b) (6) : Shen, Yuan Li  
(FDA/CDER) (b) (6) Farley, John (FDA/CDER) (b) (6) >; Goff, David (NIH/NHLBI)  
[E] (b) (6) Vincent, Michael < (b) (6)  
**Cc:** Mary Biggs < (b) (6) Demarcus < (b) (6) : Macone, Erin < (b) (6)  
Tountas, Karen (FNIH) [T] < (b) (6) : Wachtel, Jonathan (b) (6) : Elizabeth Kim  
(b) (6) >; Parker, Ashley (NIH/OD) [E] < (b) (6) Butcher, Tina  
(b) (6) Wholley, David (FNIH) [T] (b) (6) Melencio, Cheryl (FNIH) [T]  
(b) (6) Wung, Peter /US (b) (6) Qashu, Felicia (NIH/OD) [E]  
< (b) (6) Stratton, Benjamin (b) (6)  
**Subject:** Re: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Good morning all:

It would seem that our active control arm had been identified. Should we get in the queue with Gilead sooner rather than later - or have we already reached out to them?

S

---

**From:** "Adam, Stacey (FNIH) [T]" < (b) (6) >  
**Date:** Thursday, April 23, 2020 at 8:31:00 PM

APAR0000005629-2517008



To: "Bozzette, Sam (NIH/NCATS) [E]" (b) (6) >, "Butterton, Joan" <joan (b) (6)>, "Collins, Sylva (FDA/CDER)" (b) (6) >, "Judy Currier" (b) (6) >, "De Claro, R. Angelo (FDA/CDER)" (b) (6) >, "Mark Eisner" < (b) (6)>, "Keith Gottesdiener" (b) (6) >, "Eric Hughes" < (b) (6)>, "LaVange, Lisa M" (b) (6) >, "Elliott Levy" < (b) (6)>, "Sandeep Menon" (b) (6) >, "Amanda Peppercorn" (b) (6) >, "Proschan, Michael (NIH/NIAID) [E]" (b) (6) >, "Read, Sarah (NIH/NIAID) [E]" < (b) (6)>, "Amanda Peppercorn" < (b) (6)>, "Price, Dionne (FDA/CDER)" < (b) (6)>, "Rubin, Daniel B. (FDA/CDER)" (b) (6) >, "Shen, Yuan Li (FDA/CDER)" (b) (6) >, "Farley, John (FDA/CDER)" (b) (6) >, "Goff, David (NIH/NHLBI) [E]" (b) (6) >, "Vincent, Michael" (b) (6) >

Cc: "Mary Biggs" < (b) (6)>, "Demarcus" (b) (6) >, "Macone, Erin" (b) (6) >, "Tountas, Karen (FNIH) [T]" (b) (6) >, "Wachtel, Jonathan" (b) (6) >, "Elizabeth Kim" (b) (6) >, "Parker, Ashley (NIH/OD) [E]" (b) (6) >, "Butcher, Tina" (b) (6) >, "Wholley, David (FNIH) [T]" (b) (6) >, "Melencio, Cheryl (FNIH) [T]" (b) (6) >, "Wung, Peter /US" (b) (6) >, "Qashu, Felicia (NIH/OD) [E]" (b) (6) >, "Stratton, Benjamin" (b) (6) >

**Subject:** RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the materials for tomorrow's meeting.

1. Agenda
2. Slides for discussion updated with the decisions from today
3. A useful resource about current standard clinical treatment guidelines from the front lines for COVID. This may be a useful resource in selecting how to do minimal data collection and trying to understand SOC.

Please let me know if you have questions or other things you think would be helpful for the group to review.

Thanks,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnerships

Direct: (b) (6) | Mobile: (b) (6)

Join Zoom Meeting

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(b) (6) US

(b) (6) JS

JS (Houston)

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**From:** LaVange, Lisa M [ (b) (6) ]  
**Sent:** 4/30/2020 3:18:57 PM  
**To:** 'Levy, Elliott' [ (b) (6) ]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan\_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fdi]; Mark Eisner [ (b) (6) ]; Keith Gottesdiener [ (b) (6) ]; Eric Hughes [ (b) (6) ]; Sandeep Menon [ (b) (6) ]; Amanda Peppercorn [ (b) (6) ]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [ (b) (6) ]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fdi]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fdi]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fdi]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [ (b) (6) ]  
**CC:** Mary Biggs [ (b) (6) ]; DeMarcus, Forrest [ (b) (6) ]; Macone, Erin [ (b) (6) ]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) ]; Elizabeth Kim [ (b) (6) ]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [ (b) (6) ]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wung, Peter /US [ (b) (6) ]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Stratton, Benjamin [ (b) (6) ]  
**Subject:** RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

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Talk to everyone soon,  
Lisa

**From:** Levy, Elliott [mailto: (b) (6) ]  
**Sent:** Thursday, April 30, 2020 10:24 AM

APAR0000005578-2517010



**To:** LaVange, Lisa M <lisa. (b) (6)> Adam, Stacey (FNIH) [T] < (b) (6)> Bozzette, Sam (NIH/NCATS) [E] < (b) (6)> Butterson, Joan < (b) (6)> Collins, Sylva (FDA/CDER) < (b) (6)> Judy Currier < (b) (6)> De Claro, R. Angelo (FDA/CDER) < (b) (6)> Mark Eisner < (b) (6)> Keith Gottesdiener < (b) (6)> Eric Hughes < (b) (6)> Sandeep Menon < (b) (6)> Amanda Peppercorn <amanda.f. (b) (6)> Proschan, Michael (NIH/NIAID) [E] < (b) (6)> Read, Sarah (NIH/NIAID) [E] < (b) (6)> Amanda Peppercorn < (b) (6)> Price, Dionne (FDA/CDER) < (b) (6)> Rubin, Daniel B. (FDA/CDER) <daniel. (b) (6)> Shen, Yuan Li (FDA/CDER) < (b) (6)> Farley, John (FDA/CDER) < (b) (6)> Goff, David (NIH/NHLBI) [E] < (b) (6)> Vincent, Michael <Michael.Vi (b) (6)>

**Cc:** Mary Biggs < (b) (6)> DeMarcus, Forrest < (b) (6)> Macone, Erin < (b) (6)> Tountas, Karen (FNIH) [T] < (b) (6)> Wachtel, Jonathan < (b) (6)> Elizabeth Kim < (b) (6)> Parker, Ashley (NIH/OD) [E] < (b) (6)> Butcher, Tina < (b) (6)> Wholley, David (FNIH) [T] < (b) (6)> Melencio, Cheryl (FNIH) [T] < (b) (6)> Wung, Peter /US < (b) (6)> Qashu, Felicia (NIH/OD) [E] < (b) (6)> Stratton, Benjamin < (b) (6)>

**Subject:** RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

I agree that remdesivir will need to become background therapy in all treatment arms. This gives us to opportunity to test regimens which target both the virus and the host, which is exciting.

With regard to the target RRR, in my view the emerging data confirm the need to power for 1.25, rather than something larger:

-Remdesivir (a rationally designed therapy) exhibited an effect of 1.31 in ACCT1 on TTR, and a somewhat smaller effect (1.23) in the terminated Chinese trial. These are our best estimates for what a rationally designed therapy can do.

-In ACCT1, an effect of 1.31 was associated with a reduction in duration of hospital stay by 4 days, which would be meaningful from a health care system perspective.

-I would not expect other therapies we test to exhibit a larger effect than remdesivir. They were not designed to address the pathophysiology of COVID-19, about which we know little, and their benefit might be partially attenuated when used in combination with another active agent.

-A smaller effect for the experimental therapy would still be meaningful, if one could infer the combination of experimental therapy + remdesivir had an effect of 1.5 or more.

Elliott

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**From:** LaVange, Lisa M < (b) (6)>  
**Sent:** Thursday, April 30, 2020 6:50 AM  
**To:** Adam, Stacey (FNIH) [T] < (b) (6)>; Bozzette, Sam (NIH/NCATS) [E] < (b) (6)>; Butterson, Joan <j. (b) (6)> Collins, Sylva (FDA/CDER) < (b) (6)> Judy Currier < (b) (6)> De Claro, R. Angelo (FDA/CDER) < (b) (6)>; Mark Eisner < (b) (6)>; Keith Gottesdiener < (b) (6)>; Eric Hughes < (b) (6)>; Levy, Elliott <elliottl@amgen.com>; Sandeep Menon < (b) (6)>; Amanda Peppercorn < (b) (6)> Proschan, Michael (NIH/NIAID) [E] < (b) (6)> Read, Sarah (NIH/NIAID) [E] < (b) (6)>; Amanda Peppercorn < (b) (6)> Price, Dionne (FDA/CDER) < (b) (6)>; Rubin, Daniel B. (FDA/CDER) < (b) (6)> Shen, Yuan Li (FDA/CDER) < (b) (6)> Farley, John (FDA/CDER) < (b) (6)> Goff, David (NIH/NHLBI) [E] < (b) (6)> Vincent, Michael < (b) (6)>

**Cc:** Mary Biggs < (b) (6)> DeMarcus, Forrest < (b) (6)> Macone, Erin

< (b) (6) ; Tountas, Karen (FNIH) [T] < (b) (6) ; Wachtel, Jonathan (b) (6) ; Elizabeth Kim (b) (6) ; Parker, Ashley (NIH/OD) [E] (b) (6) >; Butcher, Tina (b) (6) >; Wholley, David (FNIH) [T] (b) (6) ; Melencio, Cheryl (FNIH) [T] (b) (6) ; Wung, Peter /US (b) (6) ; Qashu, Felicia (NIH/OD) [E] (b) (6) ; Stratton, Benjamin < (b) (6)

**Subject:** [External] Re: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Agree, thanks for raising this, Sam. There are other implications as well. We may need to revisit the meds we will allow as background therapy, now that we have a true standard of care consistent across all sites. And is the target RRR we want to be powered to detect (1.25) the appropriate target relative to Remdesivir?

Looking forward to talking further later today.

Lisa

---

**From:** Adam, Stacey (FNIH) [T] < (b) (6)

**Sent:** Thursday, April 30, 2020 9:44 AM

**To:** Bozzette, Sam (NIH/NCATS) [E] (b) (6) >; Butterton, Joan (b) (6) ; Collins, Sylva (FDA/CDER) (b) (6) ; Judy Currier (b) (6) ; De Claro, R. Angelo (FDA/CDER) (b) (6) >; Mark Eisner (b) (6) >; Keith Gottesdiener (b) (6) ; Eric Hughes (b) (6) ; LaVange, Lisa M (b) (6) ; Elliott Levy (b) (6) ; Sandeep Menon (b) (6) >; Amanda Peppercorn (b) (6) ; Proschan, Michael (NIH/NIAID) [E] (b) (6) >; Read, Sarah (NIH/NIAID) [E] (b) (6) ; Amanda Peppercorn (b) (6) ; Price, Dionne (FDA/CDER) (b) (6) ; Rubin, Daniel B. (FDA/CDER) (b) (6) >; Shen, Yuan Li (FDA/CDER) (b) (6) ; Farley, John (FDA/CDER) (b) (6) ; Goff, David (NIH/NHLBI) [E] (b) (6) ; Vincent, Michael (b) (6)

**Cc:** Mary Biggs (b) (6) ; DeMarcus, Forrest (b) (6) >; Macone, Erin < (b) (6) ; Tountas, Karen (FNIH) [T] < (b) (6) ; Wachtel, Jonathan (b) (6) ; Elizabeth Kim (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6) ; Butcher, Tina (b) (6) >; Wholley, David (FNIH) [T] (b) (6) ; Melencio, Cheryl (FNIH) [T] (b) (6) ; Wung, Peter /US < (b) (6) ; Qashu, Felicia (NIH/OD) [E] (b) (6) ; Stratton, Benjamin (b) (6) >

**Subject:** RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Hi Sam,

I think you are correct and we can discuss more today and tomorrow. I am currently trying to figure out what the outreach procedure should be, but I agree it likely needs to sooner rather than later.

Thanks,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnerships  
Direct: (b) (6) | Mobile: (b) (6)

---

**From:** Bozzette, Sam (NIH/NCATS) [E] (b) (6)

**Sent:** Thursday, April 30, 2020 9:19 AM

**To:** Adam, Stacey (FNIH) [T] (b) (6) ; Butterton, Joan (b) (6) ; Collins, Sylva



(FDA/CDER) (b) (6) Judy Currier (b) (6) De Claro, R. Angelo (FDA/CDER)  
 (b) (6) >; Mark Eisner (b) (6) >; Keith Gottesdiener  
 (b) (6) >; Eric Hughes (b) (6) LaVange, Lisa M < (b) (6)  
 Elliott Levy (b) (6) Sandeep Menon (b) (6) Amanda Peppercorn  
 (b) (6) ; Proschan, Michael (NIH/NIAID) [E] (b) (6) ; Read, Sarah  
 (NIH/NIAID) [E] (b) (6) >; Amanda Peppercorn (b) (6) Price, Dionne  
 (FDA/CDER) (b) (6) Rubin, Daniel B. (FDA/CDER) (b) (6) Shen, Yuan Li  
 (FDA/CDER) (b) (6) ; Farley, John (FDA/CDER) (b) (6) Goff, David (NIH/NHLBI)  
 [E] < (b) (6) Vincent, Michael (b) (6)  
**Cc:** Mary Biggs (b) (6) >; Demarcus (b) (6) >; Macone, Erin (b) (6) ;  
 Tountas, Karen (FNIH) [T] (b) (6) ; Wachtel, Jonathan < (b) (6) Elizabeth Kim  
 (b) (6) ; Parker, Ashley (NIH/OD) [E] < (b) (6) Butcher, Tina  
 (b) (6) ; Wholley, David (FNIH) [T] (b) (6) ; Melencio, Cheryl (FNIH) [T]  
 (b) (6) ; Wung, Peter /US (b) (6) Qashu, Felicia (NIH/OD) [E]  
 < (b) (6) Stratton, Benjamin (b) (6) >  
**Subject:** Re: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Good morning all:

It would seem that our active control arm had been identified. Should we get in the queue with Gilead sooner rather than later - or have we already reached out to them?

S

---

**From:** "Adam, Stacey (FNIH) [T]" (b) (6)  
**Date:** Thursday, April 23, 2020 at 8:31:00 PM  
**To:** "Bozzette, Sam (NIH/NCATS) [E]" < (b) (6) "Butterton, Joan" <joan (b) (6)  
 "Collins, Sylva (FDA/CDER)" (b) (6) "Judy Currier" (b) (6) >, "De Claro, R.  
 Angelo (FDA/CDER)" (b) (6) "Mark Eisner" (b) (6) , "Keith Gottesdiener"  
 < (b) (6) "Eric Hughes" < (b) (6) "LaVange, Lisa M"  
 < (b) (6) "Elliott Levy" (b) (6) "Sandeep Menon" (b) (6)  
 "Amanda Peppercorn" (b) (6) , "Proschan, Michael (NIH/NIAID) [E]"  
 (b) (6) , "Read, Sarah (NIH/NIAID) [E]" < (b) (6) "Amanda Peppercorn"  
 (b) (6) "Price, Dionne (FDA/CDER)" < (b) (6) "Rubin, Daniel B.  
 (FDA/CDER)" < (b) (6) "Shen, Yuan Li (FDA/CDER)" (b) (6) , "Farley, John  
 (FDA/CDER)" < (b) (6) "Goff, David (NIH/NHLBI) [E]" < (b) (6) "Vincent, Michael"  
 (b) (6)  
**Cc:** "Mary Biggs" < (b) (6) "Demarcus" (b) (6) "Macone, Erin"  
 (b) (6) "Tountas, Karen (FNIH) [T]" (b) (6) "Wachtel, Jonathan"  
 (b) (6) , "Elizabeth Kim" (b) (6) >, "Parker, Ashley (NIH/OD) [E]"  
 (b) (6) "Butcher, Tina" (b) (6) "Wholley, David (FNIH) [T]"  
 < (b) (6) >, "Melencio, Cheryl (FNIH) [T]" (b) (6) >, "Wung, Peter /US"  
 < (b) (6) >, "Qashu, Felicia (NIH/OD) [E]" (b) (6) , "Stratton, Benjamin"  
 (b) (6)  
**Subject:** RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the materials for tomorrow's meeting.

1. Agenda
2. Slides for discussion updated with the decisions from today



3. A useful resource about current standard clinical treatment guidelines from the front lines for COVID. This may be a useful resource in selecting how to do minimal data collection and trying to understand SOC.

Please let me know if you have questions or other things you think would be helpful for the group to review.

Thanks,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnerships

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US (Houston)

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Password: (b) (6)

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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 7/10/2020 2:41:18 PM  
**To:** Sandeep Menon [ (b) (6) ]; Rachel Harrigan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80023e7be2dd4554b54d1604fa60df18-rachel.h.ha]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Roger Paredes [ (b) (6) ]; Andrew Phillips [ (b) (6) ]  
**CC:** Demarcus [ (b) (6) ]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) ]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Chen, Helen Q. [ (b) (6) ]; Eron, Joseph J Jr [ (b) (6) ]; Chew, Kara M.D. [ (b) (6) ]; Daar, Eric [ (b) (6) ]; Erhardt, William (HHS/IOS) [ (b) (6) ]  
**Subject:** Canceled: ACTIV-3 Standing Protocol Team Meeting  
**Location:** <https://fnih.zoom.us> (b) (6)  
**Start:** 6/29/2020 3:00:00 PM  
**End:** 6/29/2020 4:00:00 PM  
**Show Time As:** Free

**Recurrence:** Weekly  
every Monday from 11:00 AM to 12:00 PM  
**Required Attendees:** Jens Lundgren; Wentworth, Debby; (b) (6) (b) (6) Ajay Nirula - Lilly; (b) (6) Patterson, Amy (NIH/NHLBI) [E]; Andrew Phillips; (b) (6) (b) (6) Birgit Grund ( (b) (6) (b) (6) Lane, Cliff (NIH/NIAID) [E]; (b) (6) (b) (6) Higgs, Elizabeth (NIH/NIAID) [E]; (b) (6) (b) (6) Ginny Kan; Baker, Jason; (b) (6) (b) (6) Neaton, Jim; (b) (6) Judy Currier; (b) (6) (b) (6) Reineck, Lora (NIH/NHLBI) [E]; Kozak, Marina (OS/ASPR/BARDA); Miller, Marissa A (NIH/NHLBI) [E]; Mark Polizzotto; (b) (6) (b) (6) Proschan, Michael (NIH/NIAID) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Paul Klekotka - Lilly; Harrigan, Rachel (HHS/IOS); Cavan, Reilly; Roger Paredes; (b) (6) Read, Sarah (NIH/NIAID) [E]; Shweta Sharma; Taylor Thompson; (b) (6) (b) (6) Rosenberg, Yves (NIH/NHLBI) [E]; Davey, Victoria ( (b) (6) Denning, Eileen; Larson, Gregg; Peter Smith, M.D. (Thoracic Surgery); Katharina Krapp; John Rule; Aileen M Ilaria  
**Optional Attendees:** Daniel Dawson Murray; (b) (6) Lisbeth Jørgensen; Nicole Engen; RH-FP-CHIP-ACTIV3-INSIGHT014; Tierney, John (NIH/NIAID) [E]; Marie Helleberg; Cate Carey; Vjecha, Michael; Hudson, Fleur; Pett, Sarah; Bitten Aagaard; Charlotte Bjernved Nielsen; Kent P Hassett; Lilian Gonzalez; Andrew G Koustenis; Eccard-Koons, Vanessa (NIH) [C]; Buehn, Molly (NIH) [C]; MacDonald, Leah (NIH) [C]; Ganapathy Gopalrathnam; Janice Evans; Janelle A Sabo; Carlos O Garner - Lilly; Tonya L Combs; Lori J Stephens; Lau, Chuen-Yen (NIH/NIAID) [E]; Herpin, Betsey (NIH/NIAID) [E]; Barrett, Kevin (NIH/NIAID) [E]; Smolskis, Mary (NIH/NIAID) [E]; Engel, Theresa (NIH) [C]; Osborne, Cynthia (NIH) [C]; Simpson, Shelly (NIH) [C]; Vogel, Susan (NIH/NIAID) [E]; Grace, Beth (NIH/NIAID) [C]; Proffitt, Calvin (NIH) [C]; Hohn, Matt (NIH) [C]; (b) (6) McNay, Laura (NIH/NIAID) [E]; Pierson, Jerome (NIH/NIAID) [C]; Mock, Rebecca (NIH/NIAID) [E]; Segal Raim, Sharon (NIH) [E]; Miller, Tracey (NIH) [C]; Parrish, David (NIH/NIAID) [E]; Galcik, Michael (NIH) [C]; Dighero-Kemp, Bonnie (NIH/NIAID) [C]; Hensley, Lisa (NIH/NIAID) [E]

Stacey Adam is inviting you to a scheduled Zoom meeting.

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**From:** Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]  
**Sent:** 7/8/2020 5:49:38 PM  
**To:** (b) (6); (b) (6); (b) (6); Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6); (b) (6); (b) (6); (b) (6); (b) (6); Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6); Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6); (b) (6); Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; (b) (6); Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [ (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [ (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]  
**CC:** Diamond, Michael [ (b) (6) Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Hughes, Eric [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria

[ (b) (6) Kim, Elizabeth [ (b) (6) Tolman, Brett [ (b) (6) Wachtel,  
Jonathan (b) (6) Prabhavathi Fernandes [prabha. (b) (6) Rose Li  
[ (b) (6) Dana Carluccio (b) (6) ; Lagos, Enrique (NIH/NCATS)  
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha  
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];  
Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D  
(b) (6) ; Dave Frankowski [ (b) (6) Baric, Toni C  
[ (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative  
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Nancy Haigwood  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin  
[ (b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James  
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]

**Subject:** ACTIV Preclinical full working group  
**Attachments:** 2020-07-01\_Preclinical\_WG\_Summary\_F1.docx

Dear Preclinical Working group and attendees,

I apologize for not providing the minutes from last week's meeting. Here they are for your review.

Sincerely,  
Joe

**Joseph P. Menetski Ph.D.**  
Associate Vice President, Research Partnerships  
**Foundation for the National Institutes of Health**  
(b) (6) | [fnih.org](https://fnih.org)  
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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**To:** Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Bascles, Lionel [ (b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron\_cohen]; Corey, Larry [lcorey@fredhutch.org]; Desrosiers, Betsy [ (b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; King, James (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce1f3853e43d4463a04f7d74992f96ac-James.King.]; Kurilla, Michael (NIH/NCATS) [E] [ (b) (6) Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [ (b) (6) Resnansky, Laura [ (b) (6) Srinivasan, Badhri (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [ (b) (6) Wachtel, Jonathan [ (b) (6) ]; Garner, Carlos [ (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]

**CC:** Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [ (b) (6) Jansen, Kathrin [ (b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [ (b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [ (b) (6) Carluccio, Dana [ (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [ (b) (6) Heaton, Penny [ (b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [ (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [robin\_criffield@med.unc.edu]; Minnich, Beth [ (b) (6) Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Stratton, Benjamin [ (b) (6) Tolman, Brett [ (b) (6) Kenny, Dermot [ (b) (6) (b) (6) emmanuel. (b) (6) Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; (b) (6) (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Marks,



Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5];  
 (b) (6) Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56fdb4598a57b423d484dcf9f-offit.email]; (b) (6)  
 Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccba4e3caaf5eb5d3586b1cc-Jonathan.Se];  
 (b) (6) (b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan];  
 (b) (6) (b) (6) (b) (6) (b) (6)  
 (b) (6) (b) (6) (b) (6) Johnson, Maureen  
 (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; Kozlowski, Mary  
 (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Austin, Sarah  
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Victoria Davey  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Jintanat Ananworanich  
 [ (b) (6) Michael Watson (x) [ (b) (6) Verani, Jennifer R.  
 (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Schrag, Stephanie  
 (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Marovich, Mary (NIH/NIAID)  
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]; Hamilton, Nancy  
 [ (b) (6) Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]

**Attachments:** Clinical Trial Capacity Working Group Meeting Agenda\_05122020.pdf

**Location:** https://zoom.us/ (b) (6)

**Start:** 5/12/2020 3:00:00 PM

**End:** 5/12/2020 4:00:00 PM

**Show Time As:** Busy

**Recurrence:** (none)  
every Tuesday and Friday from 9:00 AM to 10:00 AM

**Required Attendees:** Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; King, James; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzone; Resnansky, Laura; Srinivasan, Badhri; Stein, Peter (FDA/CBER); Vincent, Mike; Wachtel, Jonathan; Garner, Carlos; Sizemore, Christine (NIH/FIC) [E]; Qashu, Felicia

**Optional Attendees:** Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T]  
 (b) (6) Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] (b) (6) Stratton, Benjamin; Tolman, Brett; Kenny, Dermot; (b) (6) (b) (6) (b) (6)  
 (b) (6) (b) (6) Haynes, Barton; (b) (6)  
 (b) (6) Lowy, Douglas (NIH/NCI) [E]; Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); (b) (6) Offit, Paul; (b) (6) .com; Seals, Jonathan (OS/ASPR/BARDA); (b) (6) (b) (6) Arvin, Ann; (b) (6)  
 (b) (6) christine.van- (b) (6) (b) (6)  
 (b) (6) (b) (6) (b) (6) Johnson, Maureen (NIH/NCI) [E]; Kozlowski, Mary (NIH/NCI) [C]; Austin, Sarah (NIH/NIAID) [E]; Davey, Victoria; Jintanat Ananworanich;

Apologies for the repeat emails, updated agenda is attached. Karen

**Dear Colleagues, Attached is the meeting agenda. Looking forward to a robust discussion about vaccine protocols and capacity needs! Karen**

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,  
Karen

Karen H. Tountas, PhD  
Scientific Program Manager  
Foundation for the National Institutes of Health

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**From:** Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]  
**Sent:** 5/30/2020 12:32:00 AM  
**To:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]  
**CC:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]  
**Subject:** RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Hoping these are coming to me soon, as I may want to do some editing -- and then I wanted to run them past Janet tonight.

FC

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**From:** Wholley, David (FNIH) [T] <(b) (6)>  
**Sent:** Friday, May 29, 2020 7:41 PM  
**To:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Cc:** Adam, Stacey (FNIH) [T] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Gonzalez, Nina <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)>  
**Subject:** RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Have seen and offered a few changes to the complete slide deck. They should be coming back to you as soon as Deloitte makes the changes.

---

**From:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Sent:** Friday, May 29, 2020 5:59 PM  
**To:** Wholley, David (FNIH) [T] <(b) (6)>  
**Cc:** Adam, Stacey (FNIH) [T] <(b) (6)>; Freire, Maria (FNIH) [T] <(b) (6)> Gonzalez, Nina <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)>  
**Subject:** RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi all,

I have received information from Amy Patterson about the anticoagulant trial, and I'd like to have that incorporated into the slide set that Deloitte is currently working on. Attached is the document from Amy. I have highlighted the main points that I would want to have included in the slides, trying if possible to mirror the same features that are going to be included in the description of the immunomodulator study.

See what you think. I stand ready to look at ppts anytime this evening.

One question about the immunomodulator trial that I noticed in Moncef's note -- has FDA agreed with the plan to move straight into phase 3 from a safety and efficacy standpoint?

Thanks, Francis



**From:** Wholley, David (FNIH) [T] (b) (6)  
**Sent:** Friday, May 29, 2020 1:59 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Adam, Stacey (FNIH) [T] (b) (6); Freire, Maria (FNIH) [T] <(b) (6)>; Gonzalez, Nina (b) (6); Parker, Ashley (NIH/OD) [E] (b) (6)  
**Subject:** Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Francis:

Here is the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1; it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
- OWS/ACTIV Therapeutics has been taking a **portfolio** approach to addressing the dramatic health and economic challenges posed by the pandemic, with harmonized efforts that address both disease etiology and symptomology.
  - ACTIV Baricitinib (ACTT2, sponsored by NIAID) – in progress
  - ACTIV hiVIG (sponsored by NIAID) – in progress
  - ACTIV-1 – Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) – (Phase III) – ready to launch late June
  - ACTIV-2\* – Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) – (Phase II/III) – projected launch June
  - ACTIV-3\* – Neutralizing Monoclonal Antibodies Inpatient Master Protocol (NIAID INSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/III) – projected launch July
  - ACTIV-4 – Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually, Anticoagulant+Immune Modulator Combinations (NHLBI-NINDS "Master" Network) – (Phase II/III) – projected launch late June
  - ACTIV-5 – De Novo Master Protocol Structure to test promising agents not effectively evaluated elsewhere (e.g., antivirals) – similar design to the mAb protocols, networks/sites/agents in discussions now – projected launch August *(if needed; i.e. if agents are not incorporated into mAb protocols)*
    - \* current priority

[for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base
- Prioritization Process (v 2.0) for ACTIV : (slide 14 from May 20 EC deck)
- Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)  
[Key Criteria for Scoring (slide 15 from 5/20) can go to backup
- Prioritization and Protocol Design: Who is Involved – two-box slide containing names and affiliations of those involved in the Prioritization and MP Subgroups (quality folks!)
- ACTIV-1 Protocol for immunomodulators
  - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)
  - 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
  - All 3 either have initial Phase II data or are currently running company-sponsored Phase II trials = high POS
  - Phase III master protocol design for ACTIV-1 includes aggressive efficacy and futility assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)

- Companies have agreed to share data + common control arm+ common endpoints + DSMB = efficiency and ability to compare results across arms (this does not happen if companies test separately)
- Protocol is 80% complete
  - Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
    - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)
  - All three companies have written their sections of the protocols, which are being merged into the master design
- Working with OWS/BARDA on choice of CRO to run the trial; (b) (5)
- “ACTIV-4” Protocol for anticoagulants
  - Need bullets from NHLBI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS “network of networks” with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the clinical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley  
 Senior Vice-President, Research Partnerships  
 Foundation for the National Institutes of Health

(b) (6)

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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 4/14/2020 1:52:53 PM  
**To:** Eric Hughes [ (b) (6) ]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [ (b) (6) .com]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel (b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [ (b) (6) ]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]  
**CC:** Elizabeth Kim [ (b) (6) ]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [ (b) (6) ]; Rose Li Central Account [ (b) (6) ]; Lucas Small don [ (b) (6) ]; Salathin, Carla [ca (b) (6) (b) (6) ]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]  
**Subject:** ACTIV TX-Clinical WG Agent Prioritization Subgroup - 1st Meeting

Dear ACTIV Therapeutics-Clinical WG,

Thank you for your interest and participation in the Agent Prioritization sub-group. We are appreciative of your time and look forward to a focused discussion on identifying Review Committee members and facilitating the prioritization of credible therapeutic candidates for Covid-19.

Our first meeting will take place today, **Tuesday April 14<sup>th</sup>** from **5:30pm-6:30pm ET**. Dial-in instructions are below, similar to the zoom call we had yesterday. We wanted to notify you promptly of the meeting time and will follow up with an agenda and any necessary materials this afternoon prior to the call.

Please note that this is not a fixed timeslot for upcoming sub-group meetings. After this first sub-group meeting, we will send out a scheduling link to coordinate the best time for sub group meetings moving forward.

Kind regards,  
Stacey, on behalf of the ACTIV TX-Clinical WG

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Stacey J. Adam, PhD  
Director, Cancer  
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**From:** Brodd, Lauren (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]  
**Sent:** 8/14/2020 5:32:07 PM  
**To:** Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]  
**Subject:** RE: ACTIV website updates per EC slides/meeting today

Thanks for the update!!

---

**From:** Gadbois, Ellen (NIH/OD) [E] < (b) (6) >  
**Sent:** Friday, August 14, 2020 1:07 PM  
**To:** Brodd, Lauren (NIH/OD) [E] < (b) (6) >  
**Subject:** RE: ACTIV website updates per EC slides/meeting today

They are going to run "ACTIV-associated trials" by the Leadership committee somehow before implementing.

---

**From:** Gadbois, Ellen (NIH/OD) [E]  
**Sent:** Friday, August 14, 2020 1:04 PM  
**To:** Brodd, Lauren (NIH/OD) [E] < (b) (6) >  
**Subject:** RE: ACTIV website updates per EC slides/meeting today

Great. And FC is proposing that the talk about a label of 'ACTIV-associated trials' for things that ACTIV partner companies are pursuing but aren't technically ACTIV trials (not following an ACTIV master protocol, I guess). This would probably apply to IVIG trials (hyper immune globulin from patients). Reaction seemed positive.

---

**From:** Brodd, Lauren (NIH/OD) [E] < (b) (6) >  
**Sent:** Friday, August 14, 2020 12:35 PM  
**To:** Gadbois, Ellen (NIH/OD) [E] < (b) (6) >  
**Subject:** RE: ACTIV website updates per EC slides/meeting today

Hi Ellen,

Thanks for flagging! Ashley and I have been working with Renate and her team to revise the website to provide more detailed information about each of the working groups. In the updated version, we include language about the clinical trial capacity group being finished as of 7/31 and the vaccines group now only meeting on an ad hoc basis. Not sure the exact timeline (FNIH is currently reviewing the drafts) but those groups will be addressed when the updated version goes live.

Thanks,  
Lauren

---

**From:** Gadbois, Ellen (NIH/OD) [E] < (b) (6) >  
**Sent:** Friday, August 14, 2020 12:18 PM  
**To:** Brodd, Lauren (NIH/OD) [E] < (b) (6) >  
**Subject:** ACTIV website updates per EC slides/meeting today  
**Importance:** High

You may want to revise how the working groups are listed on the website since clinical trials capacity is done, and vaccine is suspended (may be reconvened if needed)—see slides.

**From:** Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]  
**Sent:** Thursday, August 13, 2020 10:20 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6); Disbrow, Gary (OS/ASPR/BARDA) (b) (6);  
Dolsten, Mikael (b) (6); Fauci, Anthony (NIH/NIAID) [E] (b) (6); Gibbons, Gary  
(NIH/NHLBI) [E] (b) (6); Marks, Peter (FDA/CBER) (b) (6); Pao, William  
(b) (6); Plump, Andrew <(b) (6)> Stoffels, Paul (b) (6);  
Woodcock, Janet (FDA/CDER) (b) (6); Colvis, Christine (NIH/NCATS) [E]  
(b) (6); Desrosiers, Betsy (b) (6); Eric Hughes  
(b) (6); Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E]  
<(b) (6)> Lowy, Douglas (NCI) (b) (6); Read, Sarah (NIH/NIAID) [E] (b) (6);  
Young, John <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)>  
**Cc:** Anderson, James (NIH/OD) [E] <(b) (6)> Austin, Christopher (NIH/NCATS) [E]  
(b) (6); Burklow, John (NIH/OD) [E] <(b) (6)> Castillejos, Carlos (b) (6);  
Culp, Michelle (NIH/OD) [E] (b) (6); FNIH Central Account <(b) (6)> Freire, Maria  
(FNIH) [T] (b) (6); Gadbois, Ellen (NIH/OD) [E] (b) (6); Hallett, Adrienne (NIH/OD) [E]  
(b) (6); Lane, Cliff (NIH/NIAID) [E] (b) (6); Myles, Renate (NIH/OD) [E]  
(b) (6); Parker, Ashley (NIH/OD) [E] (b) (6); Lawrence (NIH/OD) [E]  
<(b) (6)> Wolinetz, Carrie (NIH/OD) [E] (b) (6); Melencio, Cheryl (FNIH) [T]  
(b) (6); Adam, Stacey (FNIH) [T] (b) (6); Alvarez, Rosa (b) (6);  
Anderson, Margaret (b) (6); Chen, Helen (b) (6); Elsaid, Olivia  
(b) (6); Gonzalez, Nina <(b) (6)> Hawk, Harrison (b) (6);  
Menetski, Joseph (FNIH) [T] (b) (6); Santos, Michael (FNIH) [T] (b) (6); Stratton, Benjamin  
(b) (6); Tolman, Brett <(b) (6)> Tountas, Karen (FNIH) [T] (b) (6);  
Wachtel, Jonathan (b) (6)  
**Subject:** Materials for August 14 ACTIV Executive Committee Teleconference  
**Importance:** High

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from **12:00 – 1:00 PM Eastern U.S. time** tomorrow, Friday, August 14. I have also attached notes from our July 29 Leadership Team meeting as well as our last EC meeting on July 15. As you know we will be hearing from two Working Groups instead of four, **so the co-chairs have decided to make this call as well as future EC and LT calls going forward 60 minutes in length instead of 90 minutes.**

The Zoom information is:

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Please let Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley

Senior Vice-President, Research Partnerships

Foundation for the National Institutes of Health

(b) (6)

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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 4/21/2020 3:34:50 AM  
**To:** Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan\_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [ (b) (6) ]; Eisner, Mark [ (b) (6) ]; Gottesdiener, Keith [ (b) (6) ]; Hughes, Eric [ (b) (6) ]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [ (b) (6) ]; LaVange, Lisa [ (b) (6) ]; Levy, Elliot [ (b) (6) ]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [ (b) (6) ]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [naimish.patel@sanofi.com]; Peppercorn, Amanda [ (b) (6) ]; Poole, Mike [ (b) (6) ]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn [ (b) (6) ]  
**CC:** Butcher, Tina [ (b) (6) ]; Demarcus [ (b) (6) ]; Macone, Erin [ (b) (6) ]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [ (b) (6) ]; Mary Biggs [ (b) (6) ]  
**Subject:** RE: ACTIV Therapeutics-Clinical Working Group - Meeting Scheduling for the Week of Apr 27-May1

Dear ACTIV TX-Clinical WG Members,

If you have not already responded with your availability for meetings next week at the times below, please send by COB tomorrow, so we can get these held on everyone's calendars.

Thanks,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnerships  
Direct: (b) (6) | Mobile: (b) (6)



**From:** Adam, Stacey (FNIH) [T]

**Sent:** Sunday, April 19, 2020 8:04 PM

**To:** Bozzette, Sam (NIH/NCATS) [E] <(b) (6)> Butterson, Joan <(b) (6)> De Claro, R. Angelo (FDA/CDER) <(b) (6)> Draghia-Akli, Ruxandra <(b) (6)> Eisner, Mark <(b) (6)> Gottesdiener, Keith <(b) (6)> Hughes, Eric <(b) (6)> Judy Currier <(b) (6)> Kim, Elizabeth <(b) (6)> LaVange, Lisa <(b) (6)> Levy, Elliot <(b) (6)> Mellors, John <(b) (6)> Menon, Sandeep <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Patel, Naimish <(b) (6)> Peppercorn, Amanda <(b) (6)> Poole, Mike <(b) (6)> Proschan, Michael <(b) (6)> Read, Sarah <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Shen, Yuan Li (FDA/CDER) <(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> Buchman, Tim (OS/ASPR/BARDA) (CTR) <(b) (6)> Collins, Sylva (FDA/CDER) <(b) (6)> Amanda Peppercorn <(b) (6)>

**Cc:** Butcher, Tina <(b) (6)> Demarcus <(b) (6)> Macone, Erin <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)> Salathin, Carla <(b) (6)> Mary Biggs <(b) (6)>

**Subject:** ACTIV Therapeutics-Clinical Working Group - Meeting Scheduling for the Week of Apr 27-May1

**Importance:** High

Dear ACTIV Therapeutics-Clinical WG Members,

I hope you all have had a great weekend! While we have a solid agenda planned for this week, we are already looking ahead to ensure we have the time we need on your calendars for following week. With this in mind we were wondering if we could keep the same cadence of meetings next week for the main group and the subgroup that we have this week, or if we need repoll. If we keep the same cadence the meetings would on the follow days.

**Monday April 27<sup>th</sup>**

- Therapeutics Clinical Master Protocol Subgroup Meeting #5 (2:00PM – 3:00PM US EST)

**Tuesday April 28<sup>th</sup>**

- Therapeutics Clinical Master Protocol Subgroup Meeting #6 (1:00PM – 2:00PM US EST)
- Therapeutics Clinical Agent Prioritization Subgroup Meeting #4 (2:00PM – 3:00PM US EST)

**Wednesday April 29<sup>th</sup>**

- Therapeutics Clinical Agent Prioritization Subgroup Meeting #5 (2:00PM – 3:00PM US EST)

**Thursday April 30<sup>th</sup>**

- Therapeutics Clinical Work Group Meeting #4 (2:00PM – 3:00PM US EST)

Please let us know as soon as you can if these times can be held for standing meetings, understanding that we may need a few adhoc meetings, as well.

Thanks,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnerships  
Foundation for the National Institutes of Health  
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**From:** Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]  
**Sent:** 6/8/2020 6:35:39 PM  
**To:** Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [ (b) (6) Bascles, Lionel [ (b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron\_cohen]; Corey, Larry [ (b) (6) Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [ (b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Garner, Carlos [ (b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [ (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [ (b) (6) Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]; Kublin MD, MPH, James [ (b) (6) Ferguson, Sue [ (b) (6)  
**CC:** Kenny, Dermot [ (b) (6) Takas, Therese [ (b) (6) Eileen- [ (b) (6) Wachtel, Jonathan [ (b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [ (b) (6) Jansen, Kathrin [ (b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [ (b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana [ (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [ (b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [ (b) (6) ; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [ (b) (6) Hamilton, Nancy [ (b) (6) Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group



(FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Minnich, Beth  
(b) (6); Mueller-Reichenstein, Petra (b) (6) Pico, Dianna  
(NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-picodf]; Quadros, Nora  
(b) (6) Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Culp, Michelle (NIH/OD) [E]  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E]  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel];  
(b) (6)

**Subject:** ACTIV Clinical Trial Capacity Working Group - reporting meeting  
**Attachments:** Clinical Trial Capacity Working Group Meeting Agenda\_06092020.pdf  
**Location:** <https://fnih.zoom.> (b) (6)

**Start:** 6/9/2020 1:00:00 PM  
**End:** 6/9/2020 2:00:00 PM  
**Show Time As:** Tentative

**Recurrence:** Weekly  
every Tuesday from 9:00 AM to 10:00 AM  
**Required Attendees:** Stein, Peter (FDA/CDER); Vincent, Mike; Bascles, Lionel; Cohen, Myron; Corey, Larry; Davey, Victoria; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Garner, Carlos; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Mensah, George; Nayak, Seema (NIH/NIAID) [E]; Payton, Manzone; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan, Badhri; Weinmann, Gail; Kublin MD, MPH, James; Ferguson, Sue  
**Optional Attendees:** Kenny, Dermot; Takas, Therese; (b) (6) Wachtel, Jonathan; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E] (b) (6) Carluccio, Dana; Cheryl (FNIH) Melencio [T] (b) (6) Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Qashu, Felicia; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Hill, Zoe (NIH/NHLBI) [C]; Minnich, Beth; Mueller-Reichenstein, Petra; Pico, Dianna; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] (b) (6) Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E];  
(b) (6)

Dear Colleagues – Attached is the agenda for the call. Looking forward to an interesting call and your constructive dashboard feedback. Best regards, Karen

CT Capacity working group members, Many thanks for all the hard work that you have put into meeting our ACTIV mandate – looking forward to operationalizing the outcomes of your efforts. Let's continue to meet regularly through the month of June (once a week) to continue to build out the inventories of CROs/SMOs/Networks/Sites and innovation/efficiencies, where needed, and, to integrate with other ACTIV working groups in support of protocol implementation (treatment and prevention). Best regards, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

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**From:** Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]  
**Sent:** 7/17/2020 6:47:58 PM  
**To:** Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]  
**CC:** Alvarez, Rosa Maria [ (b) (6) ]  
**Subject:** RE: ACTIV Preclinical full working group

Sorry Ashley, I will follow up with Rosa to make sure you are always on the list (good list, not bad list 😊 )

Joe

---

**From:** Parker, Ashley (NIH/OD) [E] < (b) (6) >  
**Sent:** Friday, July 17, 2020 2:43 PM  
**To:** Menetski, Joseph (FNIH) [T] < (b) (6) >  
**Subject:** RE: ACTIV Preclinical full working group

Hi Joe,

Following up to let you know I did not receive the calendar invites to the preclinical subgroup meetings. I hope to be included soon.

Thank you,  
Ashley

---

**From:** Menetski, Joseph (FNIH) [T] < (b) (6) >  
**Sent:** Wednesday, July 8, 2020 2:51 PM  
**To:** Parker, Ashley (NIH/OD) [E] < (b) (6) >  
**Subject:** RE: ACTIV Preclinical full working group

Will do. I have sent a note to Rosa Alvarez to make sure you are added to the subgroups.

Joe

---

**From:** Parker, Ashley (NIH/OD) [E] < (b) (6) >  
**Sent:** Wednesday, July 8, 2020 1:52 PM  
**To:** Menetski, Joseph (FNIH) [T] < (b) (6) >  
**Subject:** RE: ACTIV Preclinical full working group

Thanks, Joe! Can you also please add me to the preclinical subgroup meetings?

Ashley

---

**From:** Menetski, Joseph (FNIH) [T] < (b) (6) >  
**Sent:** Wednesday, July 8, 2020 1:50 PM  
**To:** (b) (6) ; Hild, Sheri (NIH/OD) [E] < (b) (6) >; (b) (6) ; Baric, Ralph < (b) (6) >; (b) (6) ; Ottinger, Elizabeth (NIH/NCATS [E] < (b) (6) >; Colvis, Christine (NIH/NCATS) [E] < (b) (6) >; Hewitt, Judith (NIH/NIAID) [E] < (b) (6) >; Deming, Damon



(FDA/CDER) (b) (6) Parker, Ashley (NIH/OD) [E]  
 (b) (6) ; Adams, Peter (OS/ASPR/BARDA)  
 (b) (6) >; Rao, Srinivas (b) (6) >; Qashu, Felicia (NIH/OD) [E]  
 (b) (6) Tomas Cihlar (b) (6) ; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID  
 (USA) (b) (6) ; Punturieri, Antonello (NIH/NHLBI) [E] (b) (6) ; Charette, Marc  
 (NIH/NHLBI) [E] (b) (6) >; Fessel, Josh (NIH/NHLBI) [E] (b) (6) >  
 Cc: Diamond, Michael (b) (6) Austin, Christopher (NIH/NCATS) [E] (b) (6) ; Florence,  
 Clint (NIH/NIAID) [E] (b) (6) ; Simon, Dina (NIH/OD) [C] < (b) (6) Wholley, David (FNIH)  
 [T] (b) (6) >; Melencio, Cheryl (FNIH) [T] (b) (6) >; Colvis, Christine (NIH/NCATS) [E]  
 (b) (6) Desrosiers, Betsy (b) (6) Hughes, Eric  
 (b) (6) Jansen, Kathrin (b) (6) Kurilla, Michael (NIH/NCATS) [E]  
 (b) (6) Lowy, Douglas (NCI) < (b) (6) Read, Sarah (NIH/NIAID) [E] (b) (6) ;  
 Tountas, Karen (FNIH) [T] (b) (6) Santos, Michael (FNIH) [T] (b) (6) ; Adam, Stacey (FNIH) [T]  
 (b) (6) James, Stephanie (FNIH) [T] (b) (6) Alvarez, Rosa Maria (b) (6) >;  
 Kim, Elizabeth < (b) (6) Tolman, Brett < (b) (6) Wachtel, Jonathan  
 (b) (6) Prabhavathi Fernandes (b) (6) >; Rose Li  
 (b) (6) Dana Carluccio (b) (6) >; Lagos, Enrique (NIH/NCATS) [E]  
 < (b) (6) Jonson, Samantha (NIH/NCATS) [E] (b) (6) >; Gonzalez, Nina  
 (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] < (b) (6) ; Rodriguez, Robin D  
 (b) (6) >; Dave Frankowski (b) (6) Baric, Toni C  
 (b) (6) Lowy, Douglas (NIH/NCI) [E] (b) (6) Nancy Haigwood  
 (b) (6) Stratton, Benjamin (b) (6) Gadbois, Ellen (NIH/OD) [E]  
 (b) (6) ; Anderson, James (NIH/OD) [E] < (b) (6)

**Subject:** ACTIV Preclinical full working group

Dear Preclinical Working group and attendees,

I apologize for not providing the minutes from last week's meeting. Here they are for your review.

Sincerely,  
 Joe

Joseph P. Menetski Ph.D.  
 Associate Vice President, Research Partnerships  
 Foundation for the National Institutes of Health

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**From:** Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]  
**Sent:** 6/30/2020 2:17:53 AM  
**To:** Jansen, Kathrin [ (b) (6) ]; (b) (6); (b) (6); (b) (6); (b) (6) Gruber, Marion (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebf7a8eb8dd541b2883a966ea5afd809-GRUBER.fda]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; (b) (6); (b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001a98d300d14b20b18c01181eb843e0-Arvinam.Sta]; Nelson Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha]; Bett, Andrew J [ (b) (6) ]; Gilbert PhD, Peter B [ (b) (6) ]; Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.com]; Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA) [ (b) (6) ]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Greg Glenn [ (b) (6) ]; Cheryl Keech [ (b) (6) ]; Cavaleri Marco [ (b) (6) ]; Kelly, Beth [ (b) (6) ];  
**CC:** Tolman, Brett [ (b) (6) ]; (b) (6); (b) (6); (b) (6); (b) (6) Jeneffer Haynes [ (b) (6) ]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [ (b) (6) ]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Neil Formica (Contractor) [ (b) (6) ]; Joyce Plested [ (b) (6) ]; Kayvon Modjarrad [ (b) (6) ];  
**Subject:** Cancellation of this week's Protective Immune Responses Sub-Group meeting and additional updates  
**Attachments:** Thornburg assay work group 20200623-compressed.pptx; Assay Panel Production-JLL.pptx; 240620 ACTIV Meeting\_MSV2.0.pdf; 2020-06-24 Vaccines Working Group meeting Summary Notes.docx

Dear Protective Immune Responses Sub-Group members,

We are cancelling tomorrow's (Tuesday's) sub-group meeting, in part because of scheduling conflicts and in part because of lack of progress on the important action item of further understanding the planned innate and cellular immune analyses in the COVID-19 Prevention Network efficacy trials. We continue to work on that front.

In the meantime, you may recall from our last meeting that Janet Lathey offered this group to participate in the US Government SARS-CoV-2 Assay Working Group. We offered to attend these meetings when possible and report back. Attached are the presentations from the most recent meeting:

- Considerations of using viruses in SARS-CoV-2 neutralization assays (by Natalie)
- SARS-CoV-2 Assay Concordance Panels (by Janet Lathey)

We also plan to attend the next meeting.

In addition, because not everyone in this group is in the main Working Group, we have attached the presentation that CEPI shared last week and the associated meeting notes: slide 14 covers the assay standardization and animal model topics that CEPI plans to take on within their Enabling Sciences task forces, which may be of interest to this group. They also said that they are in contact with Janet Lathey and the USG Working Group.

Finally, we would like to make this group aware of an opportunity. The National Center for Advancing Translational Sciences (NCATS) at NIH is hosting the dashboard developed by the Clinical Trial Capacity Working Group on trial

networks and sites and survey data on therapeutic compounds; in the future this system may host additional tools and information on pre-clinical and clinical datasets. NIH staff already have access, but if anyone outside of NIH would like access, please let us know by Wednesday (this access is available only to members of the ACTIV groups).

As always, please reach out with any feedback. We look forward to connecting again soon.

Best regards,  
Brett and Mike

**Michael Santos, PhD**  
Associate Vice President, Science  
**Foundation for the National Institutes of Health**  
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**Sent:** 6/11/2020 6:59:57 PM  
**To:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Jim Neaton [ (b) (6) Jens Lundgren [ (b) (6) Eric Hughes [ (b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Karen Lynn Price [ (b) (6) LaVange, Lisa M [ (b) (6) Sandeep Menon [ (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Rachel Harrigan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80023e7be2dd4554b54d1604fa60df18-rachel.h.ha]; William Erhardt [ (b) (6) (b) (6) Gelijns, Annetine [ (b) (6) Moskowitz, Alan [ (b) (6) Ab Babiker [ (b) (6) Cavan, Reilly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=995fe0f1a53c443a832f96f003f0f2c5-cavanr.bios]; Phillips, Andrew [ (b) (6) [ (b) (6) Birgit Grund [ (b) (6) Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f2b26b051964d9da6868e53c9cc6c49-jim.cabr.um]; Joe Koopmeiners [ (b) (6) David Vock [ (b) (6) Thomas Murray [ (b) (6) Max Parmar [ (b) (6) Mark Polizzotto [ (b) (6) Ginny Kan [ (b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Baker, Jason [ (b) (6) Roger Paredes [ (b) (6) (b) (6) (b) (6) Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Emilia.bagiel (b) (6) (b) (6) Ajay Nirula [ (b) (6) Paul Klekotka [ (b) (6) (b) (6) Demarcus [ (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Chen, Helen Q. [ (b) (6) Eron, Joseph J Jr [ (b) (6) Chew, Kara M.D. [ (b) (6) Daar, Eric [ (b) (6) Bagiella, Emilia [emilia. (b) (6)]

**Subject:** ACTIV-3 Writing Team  
**Attachments:** ACTIV\_TX-Clinical\_ACTIV-3 Writing Team Meeting Agenda\_20200615.pdf;  
INSIGHT014\_ACTIV3\_protocol\_v0.44\_14June2020\_PAK\_Lilly.docx  
**Location:** https://fnih.zoom.us/ (b) (6)  
**Start:** 6/15/2020 3:00:00 PM  
**End:** 6/15/2020 4:00:00 PM

**Required Attendees:** Jim Neaton; Jens Lundgren; Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA); Patterson, Amy (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Reineck, Lora (NIH/NHLBI) [E]; Judy Currier; Karen Lynn Price; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; William Erhardt; (b) (6) Gelijns, Annetine; Moskowitz, Alan; Ab Babiker; Cavan, Reilly; Phillips, Andrew (b) (6) Birgit Grund; Neaton, Jim; Joe Koopmeiners; David Vock; Thomas Murray; Max Parmar; Mark Polizzotto; Ginny Kan; Lane, Cliff (NIH/NIAID) [E]; Baker, Jason; Roger Paredes; (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) Rosenberg, Yves (NIH/NHLBI) [E]; (b) (6)  
(b) (6) Ajay Nirula; Paul Klekotka

**Optional Attendees:** Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Parker, Ashley (NIH/OD) [E]; Chen, Helen Q.; Eron, Joseph J Jr; Chew, Kara M.D.; Daar, Eric; Bagiella, Emilia

Dear ACTIV-3 Writing Team,

Please find the agenda for today's meeting and the current version of the protocol.

Thanks,  
Stacey

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**Sent:** 6/11/2020 7:02:07 PM  
**To:** Jim Neaton [ (b) (6) ] Jens Lundgren [ (b) (6) ] Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Eric Hughes [ (b) (6) ] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Srinivasan, Badhri [ (b) (6) ] Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Tierney, John (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61553b35beb7479789a06defda628627-jtierney]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Rachel Harrigan [ (b) (6) ] William Erhardt [ (b) (6) ] Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; (b) (6) Gelijns, Annetine [ (b) (6) ] Mark Polizzotto [ (b) (6) ] Ginny Kan [ (b) (6) ] Baker, Jason [ (b) (6) ] Roger Paredes [ (b) (6) ] Thompson, Taylor, M.D. [ (b) (6) ] Babiker, Ab [a. (b) (6) ]  
**CC:** Chen, Helen Q. [ (b) (6) ] Wachtel, Jonathan [ (b) (6) ] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Desrosiers, Elizabeth A. [ (b) (6) ] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Kenny, Dermot [ (b) (6) ] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Pett, Sarah [ (b) (6) ] Grace, Beth (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75f1e9e678842258cf6472505f68cd8-bgrace]; Barrett, Kevin (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0490b8cf48984327b737d027f4fddd81-barrettk2]; Denning, Eileen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc3c18df3b7945bda704a01abd12b3b4-eileen.ccbrr]  
**Subject:** ACTIV-3 Operations Team Meeting  
**Location:** https://fnih.zoom.u (b) (6)  
**Start:** 6/16/2020 4:00:00 PM  
**End:** 6/16/2020 5:00:00 PM  
**Show Time As:** Tentative



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**Required Attendees:** Jim Neaton; Jens Lundgren; Read, Sarah (NIH/NIAID) [E]; Eric Hughes; Higgs, Elizabeth (NIH/NIAID) [E]; Srinivasan, Badhri; Goff, David (NIH/NHLBI) [E]; Nayak, Seema (NIH/NIAID) [E]; Victoria Davey; Kozak, Marina (OS/ASPR/BARDA); McNay, Laura (NIH/NIAID) [E]; Tierney, John (NIH/NIAID) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Patterson, Amy (NIH/NHLBI) [E]; Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; William Erhardt; Reineck, Lora (NIH/NHLBI) [E]; (b) (6) Gelijns, Annetine; Mark Polizzotto; Ginny Kan; Baker, Jason; Roger Paredes; Thompson, Taylor, M.D.; Babiker, Ab

**Optional Attendees:** Chen, Helen Q.; Wachtel, Jonathan; Tountas, Karen (FNIH) [T]; Desrosiers, Elizabeth A.; Kurilla, Michael (NIH/NCATS) [E]; Kenny, Dermot; Parker, Ashley (NIH/OD) [E]; Pett, Sarah; Grace, Beth (NIH/NIAID) [C]; Barrett, Kevin (NIH/NIAID) [E]; Denning, Eileen

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**To:** Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) : (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [ (b) (6) Colvis, Christine (NIH/NCATS) [E] [ (b) (6) Hewitt, Judith (NIH/NIAID) [E] (b) (6) Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [ (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [ (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6) (b) (6) Rao, Srinivas [ (b) (6) (b) (6)

**CC:** Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [ (b) (6) Kim, Elizabeth [ (b) (6) Tolman, Brett [ (b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [ (b) (6) Rose Li [ (b) (6) Dana Carluccio [ (b) (6) Lagos, Enrique (NIH/NCATS)



[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [ (b) (6) Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Dave Frankowski [ (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [ (b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Diamond, Michael [ (b) (6) Rodriguez, Robin D [ (b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Baric, Toni C [ (b) (6) Hughes, Eric [eric. (b) (6)

**Start:** 6/17/2020 2:00:00 PM  
**End:** 6/17/2020 3:00:00 PM

**Recurrence:** (none)

**Required Attendees:** (b) (6) Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6) ;  
 (b) (6) (b) (6) (b) (6) (b) (6)  
 (b) (6) (b) (6) (b) (6) (b) (6) (b)  
 (b) (6) (b) (6) (b) (6) (b) (6) (b) (6)  
 (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];  
 (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E];  
 Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E];  
 Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]  
**Optional Attendees:** Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin



**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 4/28/2020 8:37:13 PM  
**To:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [ (b) (6) ]; Read, Sarah (NIH/NIAID) [E] [ (b) (6) ]; Ruxandra Draghia-Akli [ (b) (6) ]; Mellors, John W [ (b) (6) ]; Naimish Patel [ (b) (6) ]; Colvis, Christine (NIH/NCATS) [E] [ (b) (6) ]; Young, John [ (b) (6) ]; Stein, Peter (FDA/CDER) [ (b) (6) ]; Poole, Mike [ (b) (6) ]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [ (b) (6) ]; Vincent, Michael [ (b) (6) ]; Keith Gottesdiener [ (b) (6) ]; Elliott Levy [ (b) (6) ]; Wung, Peter /US [ (b) (6) ]; Koroshetz, Walter (NIH/NINDS) [E] [ (b) (6) ]; Higgs, Elizabeth (NIH/NIAID) [E] [ (b) (6) ]; Carlos O Garner [ (b) (6) ]  
**CC:** Elizabeth Kim [ (b) (6) ]; Menetski, Joseph (FNIH) [T] [ (b) (6) ]; Alvarez, Rosa Maria [ (b) (6) ]; Salathin, Carla [ (b) (6) ]; (b) (6) ; (b) (6) ; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [ (b) (6) ]; Melencio, Cheryl (FNIH) [T] [ (b) (6) ]; Lucas Smalldon [ (b) (6) ]; Walker, Paula (NIH/NINDS) [E] [ (b) (6) ]; Ward, Jackie (NIH/NINDS) [E] [jackie. (b) (6) ]  
**Subject:** ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #6  
**Attachments:** ACTIV Therapeutics Clinical\_Agent Prioritization Sub-Group Meeting Agenda\_05012020v2.pdf  
**Location:** https://fnih.zoom. (b) (6)

**Start:** 5/1/2020 7:00:00 PM  
**End:** 5/1/2020 8:30:00 PM  
**Show Time As:** Busy

**Required Attendees:** Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner  
**Optional Attendees:** Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; (b) (6) ; (b) (6) ; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] (jackie.ward@nih.gov)

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached the agenda for today's call. We will be continuing the discussions from yesterday.

Thanks,  
Stacey

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US (Tacoma)

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**From:** Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]  
**Sent:** 4/24/2020 4:40:40 PM  
**To:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [ (b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [ (b) (6) Disbrow, Gary (OS/ASPR/BARDA) [ (b) (6) Dolsten, Mikael [ (b) (6) Erbeling, Emily (NIH/NIAID) [E] [ (b) (6) Fauci, Anthony (NIH/NIAID) [E] [ (b) (6) Hudson, Thomas [ (b) (6) James, Stephanie (FNIH) [T] [ (b) (6) Johnson, Robert (OS/ASPR/BARDA) [ (b) (6) Kramer, Lynn [ (b) (6) ]; Lane, Cliff (NIH/NIAID) [E] [ (b) (6) Marks, Peter (FDA/CBER) [ (b) (6) Marston, Hilary (NIH/NIAID) [E] [ (b) (6) Mascola, John (NIH/VRC) [E] [ (b) (6) Meeker, David [ (b) (6) Menetski, Joseph (FNIH) [T] [ (b) (6) Pangalos, Mene [ (b) (6) Pao, William [ (b) (6) Paul, Steve [ (b) (6) Perlmutter, Roger [ (b) (6) Plump, Andy [ (b) (6) Rasi, Guido [ (b) (6) ; Reed, John [ (b) (6) Rouse, Doris [ (b) (6) ; Santos, Michael (FNIH) [T] [ (b) (6) Skovronsky, Daniel [ (b) (6) Stein, Peter (FDA/CDER) [ (b) (6) Stoffels, Paul [ (b) (6) Tabak, Lawrence (NIH/OD) [E] [ (b) (6) ]; Tsai, John [ (b) (6) Vessey, Rupert [ (b) (6) ]; Virgin, Skip [ (b) (6) Woodcock, Janet (FDA/CDER) [ (b) (6) Young, John [ (b) (6) Colvis, Christine (NIH/NCATS) [E] [ (b) (6) Desrosiers, Betsy [ (b) (6) Hughes, Eric [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [ (b) (6) Lowy, Douglas (NCI) [ (b) (6) Read, Sarah (NIH/NIAID) [E] [ (b) (6) Freire, Maria (FNIH) [T] [ (b) (6) Adam, Stacey (FNIH) [T] [ (b) (6) Alvarez, Rosa [ (b) (6) Anderson, Margaret [ (b) (6) Gonzalez, Nina [ (b) (6) Kim, Elizabeth [ (b) (6) Stratton, Ben [ (b) (6) Tolman, Brett [ (b) (6) Tountas, Karen (FNIH) [T] [ (b) (6) Wachtel, Jonathan [ (b) (6) Rachel Ramoni [ (b) (6) Plenge, Robert [ (b) (6) Talley, Michael [ (b) (6) Cavaleri, Marco [ (b) (6) Lee, William [ (b) (6) Anderson, James (NIH/OD) [E] [ (b) (6) ]; Bianchi, Diana (NIH/NICHD) [E] [ (b) (6) ]; Brennan, Patti (NIH/NLM) [E] [ (b) (6) Byrnes, Noni (NIH/CSR) [E] [ (b) (6) Carter, Robert (NIH/NIAMS) [E] [ (b) (6) Glass, Roger (NIH/FIC) [E] [ (b) (6) Gregurick, Susan (NIH/OD) [E] [ (b) (6) Hodes, Richard (NIH/NIA) [E] [ (b) (6) Horsford, Jonathan (NIH/NIDCR) [E] [ (b) (6) ]; Koroshetz, Walter (NIH/NINDS) [E] [ (b) (6) .gov]; Norris, Andrea (NIH/CIT) [E] [ (b) (6) Rodgers, Griffin (NIH/NIDDK) [E] [ (b) (6) Schwetz, Tara (NIH/OD) [E] [tara. (b) (6) Sharpless, Norman (NIH/NCI) [E] [ (b) (6) Tucci, Debara (NIH/NIDCD) [E] [ (b) (6) ]; Tumminia, Santa (NIH/NEI) [E] [ (b) (6) ]; Volkow, Nora (NIH/NIDA) [E] [ (b) (6) ]; Wilder, Elizabeth (NIH/OD) [E] [ (b) (6) Wolinetz, Carrie (NIH/OD) [E] [ (b) (6) Grieder, Franziska (NIH/OD) [E] [ (b) (6) Clayton, Janine (NIH/OD) [E] [ (b) (6) Lankford, David (NIH/OD) [E] [ (b) (6) Gibbons, Gary (NIH/NHLBI) [E] [ (b) (6) ]; Zajicek, Anne (NIH/OD) [E] [ (b) (6) Koob, George (NIH/NIAAA) [E] [ (b) (6) Hallett, Adrienne (NIH/OD) [E] [ (b) (6) Valantine, Hannah (NIH/OD) [E] [ (b) (6) ]  
**CC:** Barasch, Kimberly (NIH/NIAID) [C] [ (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [ (b) (6) ]; Carver, Trea (NIH) [C] [ (b) (6) Conrad, Patricia (NIH/NIAID) [E] [ (b) (6) Hoffstetter, Renata (FNIH) [T] [rhoffstetter@fnihi.org]; IBERDEMAJ, Vaide [ (b) (6) Lagos, Enrique (NIH/NCATS) [E] [ (b) (6) ]; McManus, Ayanna (NIH/OD) [E] [ (b) (6) Melencio, Cheryl (FNIH) [T] [ (b) (6) Protasiewicz, Ann [ (b) (6) Simon, Dina (NIH/OD) [C] [ (b) (6) ]; Thomas, Ashley (FDA/CDER) [ (b) (6) ]; Wood, Gretchen (NIH/OD) [E] [ (b) (6) FNIH Central Account [ (b) (6) Sepulveda, Dorina (FNIH) [T] [ (b) (6) Li, Rose [ (b) (6) Zottoli, Jessica [ (b) (6) Lowy, Douglas (NIH/NCI) [E] [ (b) (6) Parker, Ashley (NIH/OD) [E] [ (b) (6) Gladman, Jordan (NIH/OD) [E] [ (b) (6) ]; Elsaid, Olivia [ (b) (6) Best, Cindy (NIH/NEI) [E] [ (b) (6) ]



Bronson, Charlette (NIH/NIA) [E] [ (b) (6) ]; Dzokoto-Pomenya, Caroline (NIH/OD) [C]  
 [ (b) (6) Hamid, Khawar (NIH/CSR) [E] [ (b) (6) Hardesty, Rebecca  
 (NIH/OD) [C] [ (b) (6) Hughes, Karen (NIH/OD) [E] [karen. (b) (6) Kellton, Karen  
 (NIH/OD) [C] [ (b) (6) Mowery, Penny (NIH/NIDDK) [E] [ (b) (6) New, Suzanne  
 (NIH/NIDCR) [E] [ (b) (6) Ott, Sandra (NIH/NICHD) [E] [ (b) (6) Salley, Jasmine  
 (NIH/NIDDK) [C] [ (b) (6) Schulke, Hilda (NIH/NIDA) [E] [ (b) (6) ]; Shapiro-Loser,  
 Beth (NIH/NIDDK) [E] [ (b) (6) Stover, Kathleen (NIH/FIC) [E] [ (b) (6) ]; Togashi,  
 Mieko (NIH/NCI) [E] [ (b) (6) Wade, Portia (NIH/CIT) [E] [ (b) (6) Barnett,  
 Sylvia (NIH/OD) [E] [ (b) (6) Dimishkov, Roxanne (NIH/NHLBI) [C] [ (b) (6)  
 Pirrone, Jen (NIH/OD) [E] [ (b) (6) Castillejos zenteno, Carlos [JRDUS] [ (b) (6)  
 Oresanya, Jejelola (NIH/OD) [C] [ (b) (6) ]

**Subject:** ACTIV Response Partnership Leadership Team Meeting #3

**Location:** <https://fnih.zoom.us/>, (b) (6)

**Start:** 5/6/2020 7:30:00 PM

**End:** 5/6/2020 9:00:00 PM

**Show Time As:** Tentative

**Required Attendees:** Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Collins, Francis (NIH/OD) [E]; Corey, Larry; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Pangalos, Mene; Pao, William; Paul, Steve; Perlmutter, Roger; Plump, Andy; Rasi, Guido; Reed, John; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Tsai, John; Vessey, Rupert; Virgin, Skip; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Freire, Maria (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Gonzalez, Nina; Kim, Elizabeth; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Rachel Ramoni; Plenge, Robert; Talley, Michael; Cavaleri, Marco; Lee, William; Anderson, James (NIH/OD) [E]; Bianchi, Diana (NIH/NICHD) [E]; Brennan, Patti (NIH/NLM) [E]; Byrnes, Noni (NIH/CSR) [E]; Carter, Robert (NIH/NIAMS) [E]; Glass, Roger (NIH/FIC) [E]; Gregurick, Susan (NIH/OD) [E]; Hodes, Richard (NIH/NIA) [E]; Horsford, Jonathan (NIH/NIDCR) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Norris, Andrea (NIH/CIT) [E]; Rodgers, Griffin (NIH/NIDDK) [E]; Schwetz, Tara (NIH/OD) [E]; Sharpless, Norman (NIH/NCI) [E]; Tucci, Debara (NIH/NIDCD) [E]; Tumminia, Santa (NIH/NEI) [E]; Volkow, Nora (NIH/NIDA) [E]; Wilder, Elizabeth (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Grieder, Franziska (NIH/OD) [E]; Clayton, Janine (NIH/OD) [E]; Lankford, David (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Zajicek, Anne (NIH/OD) [E]; Koob, George (NIH/NIAAA) [E]; Hallett, Adrienne (NIH/OD) [E]; Valantine, Hannah (NIH/OD) [E]

**Optional Attendees:** Barasch, Kimberly (NIH/NIAID) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Conrad, Patricia (NIH/NIAID) [E]; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Protasiewicz, Ann; Simon, Dina (NIH/OD) [C]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; FNIH Central Account; Sepulveda, Dorina (FNIH) [T]; Li, Rose; Zottoli, Jessica; Lowy, Douglas (NIH/NCI) [E]; Parker, Ashley (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]; Elsaid, Olivia; Best, Cindy (NIH/NEI) [E]; Bronson, Charlette (NIH/NIA) [E]; Dzokoto-Pomenya, Caroline (NIH/OD) [C]; Hamid, Khawar (NIH/CSR) [E]; Hardesty, Rebecca (NIH/OD) [C]; Hughes, Karen (NIH/OD) [E]; Kellton, Karen (NIH/OD) [C]; Mowery, Penny (NIH/NIDDK) [E]; New, Suzanne (NIH/NIDCR) [E]; Ott, Sandra (NIH/NICHD) [E]; Salley, Jasmine (NIH/NIDDK) [C]; Schulke, Hilda (NIH/NIDA) [E]; Shapiro-Loser, Beth (NIH/NIDDK) [E]; Stover, Kathleen (NIH/FIC) [E]; Togashi, Mieko (NIH/NCI) [E]; Wade, Portia (NIH/CIT) [E]; Barnett, Sylvia (NIH/OD) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Pirrone, Jen (NIH/OD) [E]; Castillejos zenteno, Carlos [JRDUS]; Oresanya, Jejelola (NIH/OD) [C]

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**From:** Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]  
**Sent:** 8/18/2020 2:59:40 PM  
**To:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [ (b) (6) Disbrow, Gary (OS/ASPR/BARDA) [ (b) (6) Dolsten, Mikael [ (b) (6) Fauci, Anthony (NIH/NIAID) [E] [ (b) (6) ]; Gibbons, Gary (NIH/NHLBI) [E] [ (b) (6) Marks, Peter (FDA/CBER) [ (b) (6) ]; Pao, William [ (b) (6) Plump, Andrew [ (b) (6) Stoffels, Paul [ (b) (6) Woodcock, Janet (FDA/CDER) [ (b) (6) Colvis, Christine (NIH/NCATS) [E] [ (b) (6) Desrosiers, Betsy [ (b) (6) Eric Hughes [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [ (b) (6) Lowy, Douglas (NCI) [ (b) (6) Read, Sarah (NIH/NIAID) [E] [ (b) (6) Young, John [ (b) (6) Anderson, James (NIH/OD) [E] [ (b) (6) Austin, Christopher (NIH/NCATS) [E] [ (b) (6) Burklow, John (NIH/OD) [E] [ (b) (6) Castillejos, Carlos [ (b) (6) Culp, Michelle (NIH/OD) [E] [ (b) (6) FNIH Central Account [ (b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadbois]; Hallett, Adrienne (NIH/OD) [E] [ (b) (6) ]; Lane, Cliff (NIH/NIAID) [E] [ (b) (6) Myles, Renate (NIH/OD) [E] [ (b) (6) Parker, Ashley (NIH/OD) [E] [ (b) (6) Tabak, Lawrence (NIH/OD) [E] [ (b) (6) Wolinetz, Carrie (NIH/OD) [E] [ (b) (6) Adam, Stacey (FNIH) [T] [ (b) (6) Alvarez, Rosa [ (b) (6) Anderson, Margaret [ (b) (6) Chen, Helen [ (b) (6) Elsaid, Olivia [ (b) (6) Gonzalez, Nina [ (b) (6) Hawk, Harrison [ (b) (6) Menetski, Joseph (FNIH) [T] [ (b) (6) Santos, Michael (FNIH) [T] [ (b) (6) Stratton, Benjamin [ (b) (6) Tolman, Brett [ (b) (6) Tountas, Karen (FNIH) [T] [ (b) (6) Wholley, David (FNIH) [T] [ (b) (6) Appell, Evan [ (b) (6) Sorosa, Alex [ (b) (6) Connelly, Sarah [ (b) (6) Wachtel, Jonathan [ (b) (6) ]  
**CC:** Barasch, Kimberly (NIH/NIAID) [C] [ (b) (6) Conrad, Patricia (NIH/NIAID) [E] [ (b) (6) Dimishkov, Roxanne (NIH/NHLBI) [C] [ (b) (6) McManus, Ayanna (NIH/OD) [E] [ayanna. (b) (6) ]; Perala, Mie [ (b) (6) Protasiewicz, Ann [ (b) (6) Riccobene, Kim [ (b) (6) Thomas, Ashley (FDA/CDER) [ (b) (6) ]; Wood, Gretchen (NIH/OD) [E] [ (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [cyndi. (b) (6) Carver, Trea (NIH) [C] [ (b) (6) Hughes, Karen (NIH/OD) [E] [ (b) (6) Lagos, Enrique (NIH/NCATS) [E] [ (b) (6) ]; Sepulveda, Dorina (FNIH) [T] [ (b) (6) ]; Simon, Dina (NIH/OD) [C] [ (b) (6) Tajalli, Ada (NIH/OD) [E] [ (b) (6) ]; Togashi, Mieko (NIH/NCI) [E] [ (b) (6) ]; Underwood, Nancy [ (b) (6) Zottoli, Jessica [Jessica. (b) (6) Dana Carluccio [ (b) (6) Lowy, Douglas (NIH/NCI) [E] [ (b) (6) .gov]; Hamilton, Nancy [ (b) (6) ]

**Subject:** ACTIV EC & Working Group Co-Chair Meeting

**Location:** [https://fnih.zoom. \(b\) \(6\)](https://fnih.zoom. (b) (6))

**Start:** 10/7/2020 2:00:00 PM

**End:** 10/7/2020 3:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Melencio, Cheryl (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; Culp, Michelle (NIH/OD) [E]; FNIH Central Account; Gadbois, Ellen (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lane,



Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Hawk, Harrison; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Appell, Evan; Sorosa, Alex; Connelly, Sarah

**Optional Attendees:** Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hughes, Karen (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Tajalli, Ada (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Hamilton, Nancy; Dana Carluccio; Lowy, Douglas (NIH/NCI) [E]

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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 5/7/2020 8:58:53 PM  
**To:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [ (b) (6) Butterson, Joan [ (b) (6) Collins, Sylva (FDA/CDER) (b) (6) ]; Judy Currier [ (b) (6) De Claro, R. Angelo (FDA/CDER) [ (b) (6) Mark Eisner [ (b) (6) Keith Gottesdiener [ (b) (6) Eric Hughes [ (b) (6) LaVange, Lisa M [ (b) (6) Elliott Levy [ (b) (6) Sandeep Menon [ (b) (6) Amanda Peppercorn [ (b) (6) Proschan, Michael (NIH/NIAID) [E] (b) (6) ; Read, Sarah (NIH/NIAID) [E] [ (b) (6) Amanda Peppercorn [ (b) (6) Price, Dionne (FDA/CDER) [ (b) (6) Rubin, Daniel B. (FDA/CDER) [ (b) (6) Shen, Yuan Li (FDA/CDER) [ (b) (6) Farley, John (FDA/CDER) [ (b) (6) Vincent, Michael [ (b) (6) Wung, Peter /US [ (b) (6) Karen Lynn Price [ (b) (6) Pamela Tenaerts, M.D. [ (b) (6) Patterson, Amy (NIH/NHLBI) [E] [amy.patterson@nih.gov]; Esserman, Laura [Laura. (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [ (b) (6) .gov]; James Palazzolo [j. (b) (6) Burgess, Timothy [ (b) (6) Beumont-Mauviel, Maria [JRDUS] [ (b) (6) .com]; Peeters, Monika [JRDUS] [ (b) (6) .com]; Woodfall, Brian [JRDUS] [ (b) (6) Van Heeswijk, Rolf [JRDUS] [ (b) (6) .com]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]  
**CC:** Mary Biggs [ (b) (6) Demarcus [ (b) (6) Macone, Erin [erinm@amgen.com]; Tountas, Karen (FNIH) [T] [ (b) (6) Wachtel, Jonathan [ (b) (6) Elizabeth Kim [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [ (b) (6) Wholley, David (FNIH) [T] [ (b) (6) Melencio, Cheryl (FNIH) [T] [ (b) (6) Forster, Katherine [ (b) (6) ]  
**Subject:** ACTIV TX-Clinical Master Protocol Subgroup Meeting #16  
**Location:** [https://fnih.zoom.us/j/ \(b\) \(6\)](https://fnih.zoom.us/j/ (b) (6))  
**Start:** 5/13/2020 5:00:00 PM  
**End:** 5/13/2020 6:00:00 PM  
**Show Time As:** Busy

**Required Attendees:** Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Esserman, Laura; Higgs, Elizabeth (NIH/NIAID) [E]; James Palazzolo; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters, Monika [JRDUS]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDUS]  
**Optional Attendees:** Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Forster, Katherine

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**From:** Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]  
**Sent:** 5/13/2020 1:57:04 AM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Dolsten, Mikael [ (b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Pao, William [ (b) (6) Stoffels, Paul [JJCUS] [ (b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Hughes, Eric [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [ (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Wolf-Rodda, Julie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89f0a08ab7224e0b9dc5a118ff336aff-wolfrodj]; Gonzalez, Nina [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]  
**CC:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]  
**Subject:** Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time  
**Attachments:** Agenda ACTIV EC Meeting #1 5-13-20.docx; Proposal for ACTIV leadership-vF 051220.pdf

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:  
Please see attached the agenda for our meeting tomorrow morning (via Zoom) and a copy of the letter from the Therapeutics- Clinical Working Group you received earlier today, for our discussion.

Please let Joe Menetski or Cheryl Melencio know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley  
Senior Vice-President, Research Partnerships  
Foundation for the National Institutes of Health

(b) (6)

[fnih.org](http://fnih.org)

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

*In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.*

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**Sent:** 6/8/2020 8:53:57 PM  
**To:** Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]  
**CC:** Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]  
**Subject:** RE: another member for ACTIV Clinical Trial Capacity Working Group

Hi Karen,

I hope you are well and had a great weekend!

I think FNIH has developed a process for obtaining permissions for future participants which includes asking via email after they've indicated participation with the POC – cc'ing your very own Cheryl to confirm and who's been super helpful.

Also cc'ing Renate and Lauren Brodd for awareness only. Lauren will be working closely with me and Renate, NIH OD to assist with keeping the NIH website for ACTIV up to date.

Thanks again,  
Ashley

---

**From:** Tountas, Karen (FNIH) [T] <(b) (6)>  
**Sent:** Monday, June 8, 2020 4:40 PM  
**To:** Parker, Ashley (NIH/OD) [E] <(b) (6)>  
**Cc:** Meltzer, Abbey (FNIH) [T] <(b) (6)>  
**Subject:** another member for ACTIV Clinical Trial Capacity Working Group

Hi Ashley,

I hope you had a nice weekend. Please note that the CT Capacity Working Group has a new member from AstraZeneca.

- Therese Takas  
Director, Clinical Operations  
AstraZeneca

Her email contact to obtain permission to list her on the NIH ACTIV website is [therese.takas@astrazeneca.com](mailto:therese.takas@astrazeneca.com)

Many thanks!  
Karen

**Karen H. Tountas, PhD**  
Scientific Program Manager  
Foundation for the National Institutes of Health  
(b) (6) | [fnih.org](http://fnih.org)  
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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**From:** Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 5/22/2020 2:30:59 AM  
**To:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [ (b) (6) ]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [ (b) (6) ]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [ (b) (6) ]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [ (b) (6) ]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [ (b) (6) ]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [ (b) (6) ]; Keith Gottesdiener [ (b) (6) ]; Elliott Levy [ (b) (6) ]; Wung, Peter /US [ (b) (6) ]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [ (b) (6) ]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]  
**CC:** Elizabeth Kim [ (b) (6) ]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [ (b) (6) ]; Salathin, Carla [ (b) (6) ]; [ (b) (6) ]; [ (b) (6) ]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [ (b) (6) ]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [ (b) (6) ]; Chen, Helen Q. [ (b) (6) ]

**Subject:** ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #13

**Location:** <https://fnih.zoom.us/> [ (b) (6) ]

**Start:** 5/28/2020 4:00:00 PM

**End:** 5/28/2020 5:00:00 PM

**Show Time As:** Tentative

**Required Attendees:** Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]

**Optional Attendees:** Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; [ (b) (6) ]; [ (b) (6) ]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] [ (b) (6) ]; Rose Li Central Account; Chen, Helen Q.

Stacey Adam is inviting you to a scheduled Zoom meeting.

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US (Germantown)

US (San Jose)

US (Tacoma)

US (Houston)

US (San Jose)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.u> (b) (6)



**From:** Connelly, Sarah [ (b) (6) ]  
**Sent:** 11/6/2020 2:29:28 PM  
**To:** Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m; (b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7adfcdb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [ (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [ (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)  
**CC:** Diamond, Michael [ (b) (6) ] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [ (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [ (b) (6) ] btolman [/o=ExchangeLabs/ou=Exchange Administrative Group



(FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi  
Fernandes [ (b) (6) Rose Li [ (b) (6) Dana Carluccio  
(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange  
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses];  
Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];  
Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi  
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D  
[ (b) (6) Dave Frankowski [ (b) (6) Baric, Toni C  
[ (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative  
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint  
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188];  
Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James  
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8];  
Mason, Stephen [ (b) (6) carol (b) (6) (b) (6)

**Subject:** RE: ACTIV Preclinical full working group

Dear Preclinical working group,

Next week's full working group meeting falls on Veterans Day. Would the group prefer keeping the meeting on Wednesday at its regularly scheduled time or moving it to 10-11 ET Thursday, Nov 12, 2020?

Can you please let us know which of these options work for you. We will move the meeting to the most popular option.

Best regards,  
Sarah

**Sarah Connelly, PhD**  
Deloitte Consulting, LLP  
Tel/Direct: (b) (6)  
www.deloitte.com

-----Original Appointment-----

**From:** Menetski, Joseph (FNIH) [T] < (b) (6) >

**Sent:** Friday, October 2, 2020 2:19 PM

**To:** Menetski, Joseph (FNIH) [T]; (b) (6) Hild, Sheri (NIH/OD) [E]; (b) (6)

(b) (6) (b) (6) (b) (6) (b) (6)

(b) (6) Baric, Ralph; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine  
(NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); (b) (6)

(b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];

(b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas  
Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc  
(NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)

**Cc:** Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T];  
Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah  
(NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH)

[T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; (b) (6) Connelly, Sarah;

(b) (6)

**Subject:** ACTIV Preclinical full working group

**When:** Thursday, November 5, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

**Where:** <https://fnih.zoom>. (b) (6)

While not unanimous, more people were able to make the 5<sup>th</sup> at 10am. We will go over the discussion at the Executive committee meeting, future strategic topics and then our normal reviews.

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

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JS (San Jose)

US (San Jose)

US (Tacoma)

US (Houston)

Meeting ID: (b) (6)

Passcode: (b) (6)

Find your local number: <https://fnih.zoom.u> (b) (6)

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**From:** Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]  
**Sent:** 7/16/2020 4:20:44 PM  
**To:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]  
**CC:** Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]  
**Subject:** RE: ACTIV Home Nursing Playbook ready for use!

**Flag:** Follow up

Excellent, thanks!

---

**From:** Wholley, David (FNIH) [T] <(b) (6)>  
**Sent:** Thursday, July 16, 2020 12:12 PM  
**To:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Cc:** Tountas, Karen (FNIH) [T] <(b) (6)>  
**Subject:** FW: ACTIV Home Nursing Playbook ready for use!

Since you asked...

---

**From:** Tountas, Karen (FNIH) [T] <(b) (6)>  
**Sent:** Thursday, July 16, 2020 11:05 AM  
**To:** Wholley, David (FNIH) [T] <(b) (6)>  
**Subject:** RE: ACTIV Home Nursing Playbook ready for use!

Just an FYI... I sent this final version to the ACTIV-2 ops team and received this from Judy Currier – “Thanks Karen, This is really helpful and just in time as we work to finalize our plans for home health in ACTIV-2. It will be of great value to the ACTIV-2 team.”

Good to know all that work was not in vain! Let’s hope the next four are also helpful for ACTIV. ☺

---

**From:** Tountas, Karen (FNIH) [T]  
**Sent:** Thursday, July 16, 2020 8:58 AM  
**To:** Colvis, Christine (NIH/NCATS) [E] <(b) (6)>; Hughes, Eric <(b) (6)>; Jansen, Kathrin <(b) (6)>; Lowy, Douglas (NCI) <(b) (6)>; Read, Sarah (NIH/NIAID) [E] <(b) (6)>; Young, John <(b) (6)>  
**Cc:** Adam, Stacey (FNIH) [T] <(b) (6)>; James, Stephanie (FNIH) [T] <(b) (6)>; Menetski, Joseph (FNIH) [T] <(b) (6)>; Santos, Michael (FNIH) [T] <(b) (6)>; Wholley, David (FNIH) [T] <(b) (6)>; Desrosiers, Betsy <(b) (6)>; Kurilla, Michael (NIH/NCATS) [E] <(b) (6)>; Kelly, Eileen <(b) (6)>; Wachtel, Jonathan <(b) (6)>  
**Subject:** ACTIV Home Nursing Playbook ready for use!

Dear ACTIV Working Group co-chairs,

On behalf of the ACTIV Clinical Trial Capacity Working Group, I am pleased to announce the completion of the ACTIV Home Nursing Playbook (attached). Many thanks to Betsy Desrosiers and Eileen Kelly (cc’d) and their teams at Merck and Novartis, respectively, for sharing their knowledge, lessons learned, and materials to enhance and accelerate ACTIV’s clinical trial efforts. And, many thanks to Jonathan and Olivia (Deloitte) for creating an organized and user-friendly structure for these playbooks.

We know that the ACTIV-2 operations team, who has used an earlier draft of this playbook, found the details enclosed very useful and we hope that other COVID-focused clinical trial protocol and operations teams will also. Please feel free to distribute to your teams, and provide any and all feedback (positive and constructive critiques).

Of note, Betsy and Eileen have offered to make themselves and their team members available to walk through the playbook with clinical trials teams as requested.

With best regards,  
Karen

**Karen H. Tountas, PhD**  
Scientific Program Manager  
**Foundation for the National Institutes of Health**

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 Butterson, Joan [ (b) (6) ]; De Claro, R. Angelo (FDA/CDER) [ (b) (6) ];  
 Draghia-Akli, Ruxandra [ (b) (6) ]; Gottesdiener, Keith [ (b) (6) ]; Eric Hughes [ (b) (6) ];  
 Judy Currier [ (b) (6) ]; Kim, Elizabeth [ (b) (6) ];  
 LaVange, Lisa [ (b) (6) ]; Mellors, John W [ (b) (6) ]; Menon, Sandeep [ (b) (6) ];  
 Parker, Ashley (NIH/OD) [E] [ (b) (6) ]; Patel, Naimish [ (b) (6) ];  
 Peppercorn, Amanda [ (b) (6) ]; Poole, Mike [ (b) (6) ];  
 Proschan, Michael (NIH/NIAID) [E] [ (b) (6) ]; Read, Sarah (NIH/NIAID) [E] [ (b) (6) ];  
 Santos, Michael (FNIH) [T] [ (b) (6) ]; Shen, Yuan Li (FDA/CDER) [ (b) (6) ];  
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 [ (b) (6) ]; Amanda Peppercorn [ (b) (6) ]; Higgs, Elizabeth (NIH/NIAID) [E] [ (b) (6) ];  
 [ (b) (6) ]; Koroshetz, Walter (NIH/NINDS) [E] [ (b) (6) ]; Timothy Burgess [ (b) (6) ];  
 Reineck, Lora (NIH/NHLBI) [E] [ (b) (6) ]; Aggarwal, Neil (NIH/NHLBI) [E] [ (b) (6) ];  
 Rosenberg, Yves (NIH/NHLBI) [E] [ (b) (6) ]; Goff, David (NIH/NHLBI) [E] [ (b) (6) ];  
 [ (b) (6) ]; Brown, Jeremy (NIH/NINDS) [E] [ (b) (6) ]; Gadbois, Ellen (NIH/OD) [E] [ (b) (6) ];  
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 Phillips, L Revell CIV DTRA RD (USA) [ (b) (6) ]; Petrovick, Martha - 0449 - MITLL [ (b) (6) ];  
 [ (b) (6) ]; Sizemore, Christine (NIH/FIC) [E] [ (b) (6) ];  
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**CC:** Colvis, Christine (NIH/NCATS) [E] [ (b) (6) ]; Jansen, Kathrin [ (b) (6) ]; Lowy, Douglas (NCI) [ (b) (6) ];  
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 Menetski, Joseph (FNIH) [T] [ (b) (6) ]; Dana Carluccio [ (b) (6) ];  
 Rose Li Central Account [ (b) (6) ]; Lucas Smalldon [ (b) (6) ];  
 [ (b) (6) ]; Mollica, Linda /US [ (b) (6) ];  
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 Rubin, Daniel B. (FDA/CDER) [ (b) (6) ]; Marston, Hilary (NIH/NIAID) [E] [ (b) (6) ];  
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 Groesch, Mary (NIH/NHLBI) [E] [ (b) (6) ]; Shipp, Allan (NIH/NHLBI) [E] [ (b) (6) ];  
 Kindzelski, Andrei (NIH/NHLBI) [E] [ (b) (6) ]; Hone, David M (Dave) CIV DTRA J9 (USA) [david.m. (b) (6) ];  
 Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [ (b) (6) ];  
 Walker, Paula (NIH/NINDS) [E] [ (b) (6) ]; Sorosa, Alex David [ (b) (6) ];  
 Lumsden, Joanne (NIH/NCATS) [C] [ (b) (6) ]; Lerner, Andrea (NIH/NIAID) [E] [ (b) (6) ];  
 Embry, Alan (NIH/NIAID) [E] [ (b) (6) ]; Dally, Nicolle [ (b) (6) ]

**Start:** 4/22/2021 5:00:00 PM  
**End:** 4/22/2021 6:00:00 PM

**Recurrence:** (none)



**From:** Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]  
**Sent:** 4/24/2020 4:46:03 PM  
**To:** Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [ (b) (6) Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [ (b) (6) Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Hudson, Thomas [ (b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [lynn\_kramer@eisai.com]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [ (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Pangalos, Mene [ (b) (6) Pao, William [ (b) (6) Paul, Steve [ (b) (6) Perlmutter, Roger [ (b) (6) Plump, Andy [ (b) (6) Rasi, Guido [ (b) (6) Reed, John [ (b) (6) Rouse, Doris [ (b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [ (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [ (b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Tsai, John [ (b) (6) Vessey, Rupert [ (b) (6) Virgin, Skip [ (b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [ (b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Hughes, Eric [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [ (b) (6) Anderson, Margaret [ (b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Kim, Elizabeth [ (b) (6) Stratton, Ben [ (b) (6) Tolman, Brett [ (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group



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(b) (6)

**CC:** Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter]; Iberdemaj, Vaide [ (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Protasiewicz, Ann [ (b) (6) Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; FNIH Central Account [ (b) (6) Li, Rose [ (b) (6)

**Subject:** ACTIV Response Partnership Leadership Team Meeting #4

**Location:** Dial-in coordinates to be supplied

**Start:** 5/20/2020 7:30:00 PM

**End:** 5/20/2020 9:00:00 PM

**Show Time As:** Tentative

**Required Attendees:** Austin, Christopher (NIH/NCATS) [E]; Collins, Francis (NIH/OD) [E]; Corey, Larry; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Pangalos, Mene; Pao, William; Paul, Steve; Perlmutter, Roger; Plump, Andy; Rasi, Guido; Reed, John; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Tsai, John; Vessey, Rupert; Virgin, Skip; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Freire, Maria (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Gonzalez, Nina; Kim, Elizabeth; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan

**Optional Attendees:** Barasch, Kimberly (NIH/NIAID) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Conrad, Patricia (NIH/NIAID) [E]; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Protasiewicz, Ann; Simon, Dina (NIH/OD) [C]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]; FNIH Central Account; Li, Rose

Dial-in coordinates to be supplied at a later date

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**Sent:** 7/1/2020 10:33:10 AM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]  
**CC:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Allen-Gifford, Patrice (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67262490d6d441b48efec1aff0700250-allengiffor]  
**Subject:** RE: ACTIV Invitations for Leadership Meeting 6/3  
**Attachments:** RE: GSK follow up on FNIH COVID call; RE: URGENT: Invitation to join the Vaccines Working Group of the COVID PPP; RE: Other Companies to give a heads up

Hi Francis and David,

ES did not find emails inviting John Lepore, GSK and David Reese, Amgen to join the ACTIV leadership group. Invitations to GSK's Emmanuel Hannon, David Payne, and Amanda Peppercorn were sent to join the vaccines, preclinical, and clinical capacity WGs. John Lepore responded to Francis' email inviting Hannon to join the GSK vaccine WG – 2<sup>nd</sup> attachment. David Reese did not receive an invitation considering Amgen already had Elliott Levy on the TX clinical working group – last attachment.

We would need to send notes if they should join the leadership meeting tomorrow and include one to Kara Carter.

Please let me know if you need anything else.

Thanks,  
Ashley

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**From:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Sent:** Monday, June 1, 2020 9:03 PM  
**To:** Wholley, David (FNIH) [T] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)>  
**Cc:** Melencio, Cheryl (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Allen-Gifford, Patrice (NIH/OD) [E] <(b) (6)>  
**Subject:** RE: ACTIV Invitations for Leadership Meeting 6/3

I also thought we reached out to Lepore and Reese, but I can't locate those e-mails. I'm looping in Exec Sec to see if they can find something.

FC

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**From:** Wholley, David (FNIH) [T] <(b) (6)>  
**Sent:** Monday, June 1, 2020 6:10 PM  
**To:** Parker, Ashley (NIH/OD) [E] <(b) (6)> ; Collins, Francis (NIH/OD) [E] <(b) (6)>



**Cc:** Melencio, Cheryl (FNIH) [T] (b) (6) Adam, Stacey (FNIH) [T] (b) (6) ; Menetski, Joseph (FNIH) [T] (b) (6) ; Tountas, Karen (FNIH) [T] < (b) (6) ; Santos, Michael (FNIH) [T] (b) (6)

**Subject:** RE: ACTIV Invitations for Leadership Meeting 6/3

I thought we had invited John Lepore from GSK and David Reese from Amgen? If not, we should. I would not invite BMGF – their relationship as observer is clear, and we could certainly ask about Evotech, since Kara Carter has been very good from what I have heard.

---

**From:** Parker, Ashley (NIH/OD) [E] (b) (6)

**Sent:** Monday, June 1, 2020 5:37 PM

**To:** Collins, Francis (NIH/OD) [E] (b) (6) ; Wholley, David (FNIH) [T] (b) (6)

**Cc:** Melencio, Cheryl (FNIH) [T] (b) (6)

**Subject:** Re: ACTIV Invitations for Leadership Meeting 6/3

Hi Francis and David,

We did not have the opportunity to discuss the difference between participants and ACTIV leadership orgs on the 5/21 war room call – Francis was unexpectedly pulled into another meeting. A small number of companies/foundations were not originally listed as leadership partners with ACTIV, therefore they were not included in previous leadership meetings. As of May 20<sup>th</sup>, we currently have all partners listed on the ACTIV webpage as leadership.

I wanted to raise the question – do we need to invite a member from Amgen, Evotec, GSK, and BMGF to the leadership meeting on Wednesday and include for future meetings?

Thank you,  
Ashley

---

**From:** Parker, Ashley (NIH/OD) [E]

**Sent:** Wednesday, May 20, 2020 10:51 AM

**To:** Wholley, David (FNIH) [T] (b) (6)

**Cc:** Melencio, Cheryl (FNIH) [T] (b) (6)

**Subject:** Re: FOR YOUR REVIEW: ACTIV Web Page Updates

Hi David,

OCPL is in the process of finalizing the [ACTIV webpage](#) and Francis asked to include BMGF as a non-profit organization and I let him know they are not one of the “leadership organizations”, along with a few companies, and academics which are not included. Francis would like to discuss on our war room call tomorrow morning – he’s not clear on the distinction between participants and leadership group members.

I’ve worked with Cheryl to figure out who is currently on the leadership list and identified who is not to help with sorting this out.

**Non leadership partners:**

- Companies: (Amgen, Evotec, GSK) – seems there should be more here?
- Non-profits: BMGF
- Academics: all

**Leadership partners:**

- 7 government: NIH, FDA, BARDA, CDC, VA, DOD, EMA,

- 16 companies: Pfizer, AbbVie, Eisai, Gilead, KSQ Therapeutics, AstraZeneca, Roche/Genentech, Karuna Therapeutics, Merck, Takeda, Sanofi, Eli Lilly, J&J, Novartis, BMS, Vir Bio
- Non-profit: FNIH, Fred Hutchinson Cancer Research Center, RTI International

All companies along with BMGF are listed on the [ACTIV webpage](#). Depending on the outcome of our discussion tomorrow, we may need to change the language on the webpage.

Thanks,  
Ashley

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**From:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Sent:** Wednesday, May 20, 2020 10:02 AM  
**To:** Parker, Ashley (NIH/OD) [E] (b) (6) >; Myles, Renate (NIH/OD) [E] (b) (6)  
**Cc:** Tabak, Lawrence (NIH/OD) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6);  
 Wolinetz, Carrie (NIH/OD) [E] (b) (6)  
**Subject:** RE: FOR YOUR REVIEW: ACTIV Web Page Updates

I guess I'm not quite clear on the distinction between participants and leadership group members. Maybe we can discuss at our next War Room conversation?

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**From:** Parker, Ashley (NIH/OD) [E] (b) (6)  
**Sent:** Wednesday, May 20, 2020 9:57 AM  
**To:** Myles, Renate (NIH/OD) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Tabak, Lawrence (NIH/OD) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6);  
 Wolinetz, Carrie (NIH/OD) [E] (b) (6)  
**Subject:** RE: FOR YOUR REVIEW: ACTIV Web Page Updates

Hi Francis and Renate,

Francis – we originally decided not to include all organizations represented on the WGs for the list of “leadership organizations” — BMGF, a small group of companies, and academics are not included.

Is the preference to list BMGF as a leadership organization? If so, we will need to invite someone from BMGF to join the ACTIV leadership group.

Looks great, Renate. The new EC members: Gary Disbrow, BARDA; Peter Marks, FDA; Andrew (Andy) Plump, Takeda.

Thank you,  
Ashley

---

**From:** Myles, Renate (NIH/OD) [E] (b) (6)  
**Sent:** Wednesday, May 20, 2020 8:05 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6) >  
**Cc:** Burklow, John (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6);  
 Parker, Ashley (NIH/OD) [E] (b) (6)  
**Subject:** RE: FOR YOUR REVIEW: ACTIV Web Page Updates

Great, thanks Francis. I'll add BMGF.

Ashley: would you send me the list of the additional EC members?

---

**From:** Collins, Francis (NIH/OD) [E] <(b) (6)>

**Sent:** Wednesday, May 20, 2020 6:44 AM

**To:** Myles, Renate (NIH/OD) [E] <(b) (6)>; Tabak, Lawrence (NIH/OD) [E] <(b) (6)>

**Cc:** Burklow, John (NIH/OD) [E] <(b) (6)>; Wolinetz, Carrie (NIH/OD) [E] <(b) (6)>;

Parker, Ashley (NIH/OD) [E] <(b) (6)>

**Subject:** RE: FOR YOUR REVIEW: ACTIV Web Page Updates

Looking good. I prefer the org chart with rectangles instead of circles. Note that we are adding three more members to the Exec Comm today, and that will need to be reflected. I also think we should include BMGF in the non-profit category – they have reps on three of the WGs and have been engaged.

FC

---

**From:** Myles, Renate (NIH/OD) [E] <(b) (6)>

**Sent:** Tuesday, May 19, 2020 9:40 PM

**To:** Collins, Francis (NIH/OD) [E] <(b) (6)>; Tabak, Lawrence (NIH/OD) [E] <(b) (6)>

**Cc:** Burklow, John (NIH/OD) [E] <(b) (6)>; Wolinetz, Carrie (NIH/OD) [E] <(b) (6)>;

Parker, Ashley (NIH/OD) [E] <(b) (6)>

**Subject:** FOR YOUR REVIEW: ACTIV Web Page Updates

Hi Francis and Larry:

We soft launched the [ACTIV webpage](#) pretty quickly with the intention of spiffing it up a bit with a little more time. Attached is a PDF version of the website with a few graphical touches to the main and leadership pages, and another PDF with slightly revised presentation of the organization chart. Let me know if the treatment and images look okay to you and we'll have the online branch incorporate them on the page. Once completed, we'll do a harder launch of the webpage with a feature on the NIH.gov homepage and some social media promotion.

Thanks,  
Renate



---

**From:** Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]  
**Sent:** 7/10/2020 2:22:08 AM  
**To:** (b) (6)  
**CC:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]  
**Subject:** Invitation to Join ACTIV Leadership Team

Dear Mr. Erck,

I greatly appreciate Gregory Glenn serving on the ACTIV vaccines working group as a representative for Novavax. We have lots of activity across our ACTIV working groups moving at rapid speed. ACTIV (Accelerating COVID-19 Therapeutic Interventions and Vaccines) has a leadership team that meets once a month to discuss progress and we typically invite the CEO's of the biotech companies to join. It would be great to have you join future leadership meetings to represent Novavax as a partner.

Please let me know if you would be able to join our leadership team and David Wholley, cc'd who manages the ACTIV partnership will ensure you receive the meeting invite for our next meeting scheduled for Wednesday, July 29, 2:30-4:00pm.

Thanks,  
Francis

Francis Collins M.D., Ph.D.  
NIH Director

**To:** Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] (b) (6) Colvis, Christine (NIH/NCATS) [E] (b) (6) ]; Hewitt, Judith (NIH/NIAID) [E] (b) (6) Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [ (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Isis. (b) (6) (b) (6) (b) (6) Rao, Srinivas (b) (6) (b) (6) (b) (6)

**CC:** Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [ (b) (6) Kim, Elizabeth (b) (6) btolman (b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes (b) (6) Rose Li (b) (6) Dana Carluccio (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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 [/o=ExchangeLabs/ou=Exchange Administrative Group  
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(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Dave Frankowski  
 [ (b) (6) antoinette\_baric [ (b) (6) Lowy, Douglas  
(NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID)  
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Stratton, Benjamin  
 [ (b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 [ (b) (6) Mason, Stephen (b) (6) Connelly, Sarah [ (b) (6)  
Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent Lloyd  
 [ (b) (6) (b) (6) (b) (6) Rodriguez, Robin D  
 [ (b) (6) (b) (6) .com; Diamond, Michael [ (b) (6) Nancy Haigwood  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Gonzalez, Nina  
 [ (b) (6)

**Start:** 2/3/2021 3:00:00 PM  
**End:** 2/3/2021 4:00:00 PM

**Recurrence:** (none)



**From:** Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]  
**Sent:** 8/18/2020 3:07:28 PM  
**To:** Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]  
**Subject:** Fwd: Notes from Friday's ACTIV Executive Committee & Working Group Co-chair Call  
**Attachments:** image001.png; ATT00001.htm; 2020-08-14\_Executive\_Committee\_Meeting\_Summary vFinal.docx; ATT00002.htm

Begin forwarded message:

**From:** "Wholley, David (FNIH) [T]" <(b) (6)>  
**Date:** August 18, 2020 at 9:16:02 AM EDT  
**To:** "Collins, Francis (NIH/OD) [E]" <(b) (6)> "Disbrow, Gary (OS/ASPR/BARDA)" <(b) (6)> "Dolsten, Mikael" <(b) (6)> "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)> "Gibbons, Gary (NIH/NHLBI) [E]" <(b) (6)> "Marks, Peter (FDA/CBER)" <(b) (6)> "Pao, William" <(b) (6)> "Plump, Andrew" <(b) (6)> "Stoffels, Paul" <(b) (6)> "Woodcock, Janet (FDA/CDER)" <(b) (6)> "Colvis, Christine (NIH/NCATS) [E]" <(b) (6)> "Desrosiers, Betsy" <(b) (6)> Eric Hughes <(b) (6)> "Jansen, Kathrin" <(b) (6)> "Kurilla, Michael (NIH/NCATS) [E]" <(b) (6)> "Lowy, Douglas (NCI)" <(b) (6)> "Read, Sarah (NIH/NIAID) [E]" <(b) (6)> "Young, John" <(b) (6)>  
**Cc:** "Adam, Stacey (FNIH) [T]" <(b) (6)> "Alvarez, Rosa" <(b) (6)> "Anderson, Margaret" <(b) (6)> "Chen, Helen" <(b) (6)> "Elsaid, Olivia" <(b) (6)> "Gonzalez, Nina" <(b) (6)> "Hawk, Harrison" <(b) (6)> "Menetski, Joseph (FNIH) [T]" <(b) (6)> "Santos, Michael (FNIH) [T]" <(b) (6)> "Stratton, Benjamin" <(b) (6)> "Tolman, Brett" <(b) (6)> "Tountas, Karen (FNIH) [T]" <(b) (6)> "Wachtel, Jonathan" <(b) (6)> "Wholley, David (FNIH) [T]" <(b) (6)> "Anderson, James (NIH/OD) [E]" <(b) (6)> "Austin, Christopher (NIH/NCATS) [E]" <(b) (6)> "Burklow, John (NIH/OD) [E]" <(b) (6)> "Castillejos, Carlos" <(b) (6)> "Culp, Michelle (NIH/OD) [E]" <(b) (6)> FNIH Central Account <(b) (6)> "Freire, Maria (FNIH) [T]" <(b) (6)> "Gadbois, Ellen (NIH/OD) [E]" <(b) (6)> "Hallett, Adrienne (NIH/OD) [E]" <(b) (6)> "Lane, Cliff (NIH/NIAID) [E]" <(b) (6)> "Myles, Renate (NIH/OD) [E]" <(b) (6)> "Parker, Ashley (NIH/OD) [E]" <(b) (6)> "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)> "Wolinetz, Carrie (NIH/OD) [E]" <(b) (6)> "Melencio, Cheryl (FNIH) [T]" <(b) (6)>  
**Subject:** Notes from Friday's ACTIV Executive Committee & Working Group Co-chair Call

Dear ACTIV Executive Committee Members and meeting attendees:

Please find attached the notes from our Friday, August 14 ACTIV Executive Committee meeting. As always, please email me with any concerns, questions, or additional comments.

Regards,  
David

APAR0000010487-2517043

**David Wholley**  
Senior Vice President, Research Partnerships  
**Foundation for the National Institutes of Health**

(b) (6)

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Donate to the FNIH's Pandemic Response Fund to combat COVID-19: [fnih.org/pandemic](https://fnih.org/pandemic)

**From:** Proschan, Michael (NIH/NIAID) [E] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=7B45059209B4468BB4BA02B0DFBBB3E4-PROSCHAM]  
**Sent:** 4/29/2020 5:36:12 PM  
**To:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan\_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coll]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [ (b) (6) Keith Gottesdiener [ (b) (6) Eric Hughes [ (b) (6) LaVange, Lisa M [ (b) (6) Elliott Levy [ (b) (6) Sandeep Menon [ (b) (6) Amanda Peppercorn [ (b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [ (b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f29042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [ (b) (6) Wung, Peter /US [ (b) (6)  
**CC:** Mary Biggs [ (b) (6) Demarcus [ (b) (6) Macone, Erin [ (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) Elizabeth Kim [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [ (b) (6) ]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]  
**Subject:** RE: Has ACTT1 been stopped?

<https://www.youtube.com/watch?v=0HujdC7s3tM>

**From:** Adam, Stacey (FNIH) [T] < (b) (6) >  
**Sent:** Wednesday, April 29, 2020 1:27 PM  
**To:** Bozzette, Sam (NIH/NCATS) [E] < (b) (6) > Butterson, Joan < (b) (6) > Collins, Sylva (FDA/CDER) < (b) (6) > Judy Currier < (b) (6) > De Claro, R. Angelo (FDA/CDER) < (b) (6) > Mark Eisner < (b) (6) > Keith Gottesdiener < (b) (6) > Eric Hughes < (b) (6) > LaVange, Lisa M < (b) (6) > Elliott Levy < (b) (6) > Sandeep Menon < (b) (6) > Amanda Peppercorn < (b) (6) > Proschan, Michael (NIH/NIAID) [E] < (b) (6) > Read, Sarah (NIH/NIAID) [E] < (b) (6) > Amanda Peppercorn < (b) (6) > Price, Dionne



(FDA/CDER) < (b) (6) Rubin, Daniel B. (FDA/CDER) < (b) (6) Shen, Yuan Li  
(FDA/CDER) < (b) (6) Farley, John (FDA/CDER) < (b) (6) Goff, David (NIH/NHLBI)  
[E] < (b) (6) Vincent, Michael < (b) (6) Wung, Peter /US  
<Peter. (b) (6)  
**Cc:** Mary Biggs < (b) (6) Demarcus < (b) (6) Macone, Erin < (b) (6)  
Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan < (b) (6) Elizabeth Kim  
< (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Butcher, Tina  
< (b) (6) Wholley, David (FNIH) [T] < (b) (6) Melencio, Cheryl (FNIH) [T]  
< (b) (6)

**Subject:** RE: Has ACTT1 been stopped?

Hi Sam,

DSMB was this week to review interim results, though the trial has fully accrued, so the interim may quickly transition to final. However, we were only expecting some blinded results to point us in the right direction next week. I will let Michael or others weigh in if my understanding was in correct.

Thanks,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnerships  
Direct: (b) (6) | Mobile: (b) (6)

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**From:** Bozzette, Sam (NIH/NCATS) [E] < (b) (6) >  
**Sent:** Wednesday, April 29, 2020 1:22 PM  
**To:** Adam, Stacey (FNIH) [T] < (b) (6) > Butterson, Joan <joan (b) (6) > Collins, Sylva  
(FDA/CDER) < (b) (6) > Judy Currier < (b) (6) > De Claro, R. Angelo (FDA/CDER)  
< (b) (6) > Mark Eisner < (b) (6) > Keith Gottesdiener  
< (b) (6) > Eric Hughes < (b) (6) > LaVange, Lisa M < (b) (6) >  
Elliott Levy < (b) (6) > Sandeep Menon < (b) (6) > Amanda Peppercorn  
< (b) (6) > Proshan, Michael (NIH/NIAID) [E] < (b) (6) > Read, Sarah  
(NIH/NIAID) [E] < (b) (6) > Amanda Peppercorn < (b) (6) > Price, Dionne  
(FDA/CDER) < (b) (6) > Rubin, Daniel B. (FDA/CDER) < (b) (6) > Shen, Yuan Li  
(FDA/CDER) < (b) (6) > Farley, John (FDA/CDER) < (b) (6) > Goff, David (NIH/NHLBI)  
[E] < (b) (6) > Vincent, Michael < (b) (6) > Wung, Peter /US  
< (b) (6) >  
**Cc:** Mary Biggs < (b) (6) > Demarcus < (b) (6) > Macone, Erin < (b) (6) >  
Tountas, Karen (FNIH) [T] < (b) (6) > Wachtel, Jonathan < (b) (6) > Elizabeth Kim  
< (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) > Butcher, Tina  
<tina (b) (6) > Wholley, David (FNIH) [T] < (b) (6) > Melencio, Cheryl (FNIH) [T]  
< (b) (6) >

**Subject:** Has ACTT1 been stopped?

<https://www.cnn.com/2020/04/29/dr-anthony-fauci-says-data-from-remdesivir-coronavirus-drug-trial-shows-quite-good-news.html>

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**From:** Bozzette, Sam (NIH/NCATS) [E]  
**Sent:** Wednesday, April 29, 2020 9:19 AM  
**To:** Adam, Stacey (FNIH) [T] < (b) (6) > Butterson, Joan <joan (b) (6) > Collins, Sylva  
(FDA/CDER) < (b) (6) > Judy Currier < (b) (6) > De Claro, R. Angelo (FDA/CDER)

< (b) (6) Mark Eisner < (b) (6) Keith Gottesdiener  
 < (b) (6) Eric Hughes < (b) (6) LaVange, Lisa M < (b) (6)  
 Elliott Levy < (b) (6) Sandeep Menon < (b) (6) Amanda Peppercorn  
 < (b) (6) Proschan, Michael (NIH/NIAID) [E] < (b) (6) Read, Sarah  
 (NIH/NIAID) [E] < (b) (6) Amanda Peppercorn < (b) (6) Price, Dionne  
 (FDA/CDER) < (b) (6) Rubin, Daniel B. (FDA/CDER) < (b) (6) Shen, Yuan Li  
 (FDA/CDER) < (b) (6) Farley, John (FDA/CDER) < (b) (6) Goff, David (NIH/NHLBI)  
 [E] < (b) (6) Vincent, Michael < (b) (6) Wung, Peter /US  
 < (b) (6)  
**Cc:** Mary Biggs < (b) (6) Demarcus < (b) (6) Macone, Erin < (b) (6)  
 Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan < (b) (6) Elizabeth Kim  
 < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Butcher, Tina  
 (b) (6) > (b) (6) Wholley, David (FNIH) [T] < (b) (6) Melencio, Cheryl (FNIH) [T]  
 < (b) (6)

**Subject:** Of interest re remdesivir

[https://www.statnews.com/2020/04/29/gilead-says-critical-study-of-covid-19-drug-shows-patients-are-responding-to-treatment/?utm\\_source=STAT+Newsletters&utm\\_campaign=f9a2a59829-breaking\\_COPY\\_01&utm\\_medium=email&utm\\_term=0\\_8cab1d7961-f9a2a59829-152058113](https://www.statnews.com/2020/04/29/gilead-says-critical-study-of-covid-19-drug-shows-patients-are-responding-to-treatment/?utm_source=STAT+Newsletters&utm_campaign=f9a2a59829-breaking_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-f9a2a59829-152058113)

-----Original Appointment-----

**From:** Adam, Stacey (FNIH) [T] < (b) (6) >

**Sent:** Wednesday, April 29, 2020 2:44 AM

**To:** Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; LaVange, Lisa M; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US

**Cc:** Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

**Subject:** Canceled: ACTIV TX-Clinical Master Protocol Subgroup Meeting #11

**When:** Wednesday, April 29, 2020 3:00 PM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).

**Where:** <https://fnih.zoom.us/j/9181212345> (b) (6)

**Importance:** High

Dear TX-Clinical Master Protocol Subgroup,

The co-chairs and subgroup chair have decide that the best use of the group's time is to hold off and reconvene with CTC WG at 12pm ET on Thursday and as our team on Friday. For Thursday, you should have an invite from Karent Tountas for the meeting with the CTC group.

See you all Thursday!

Stacey

Join Zoom Meeting

<https://fnih.zoom.us/j/9181212345> (b) (6)

Meeting ID: (b) (6)

Password: (b) (6)

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(b) (6)

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Dial by your location

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US (Chicago)  
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US (Houston)  
US (San Jose)  
US (San Jose)  
US

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)



**From:** Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]  
**Sent:** 7/21/2020 7:13:59 PM  
**To:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [ (b) (6) Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Pao, William [ (b) (6) Stoffels, Paul [ (b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [ (b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Plump, Andrew [ (b) (6) ]  
**CC:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [ (b) (6) Anderson, Margaret [ (b) (6) Chen, Helen [ (b) (6) Elsaid, Olivia [ (b) (6) Gonzalez, Nina [ (b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Benjamin [ (b) (6) Tolman, Brett [ (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Castillejos, Carlos [ (b) (6) ]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; FNIH Central Account [ (b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group



(FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Myles, Renate (NIH/OD) [E]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Parker, Ashley (NIH/OD) [E]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Tabak, Lawrence (NIH/OD)  
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Burrus-Shaw, Cyndi (NIH/OD)  
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lagos, Enrique  
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Sepulveda, Dorina (FNIH)  
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD)  
 [C] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Gorman, Greta (FNIH) [T]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Meltzer, Abbey (FNIH)  
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Barasch, Kimberly  
 (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia  
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne  
 (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; McManus, Ayanna  
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Perala, Mie  
 (b) (6) ]; Protasiewicz, Ann (b) (6) ); Riccobene, Kim  
 (b) (6) ]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen  
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Togashi, Mieko (NIH/NCI)  
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Underwood, Nancy  
 [ (b) (6) Zottoli, Jessica | (b) (6) Lowy, Douglas (NIH/NCI) [E]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Hawk, Harrison  
 [ (b) (6) Lucas Smalldon | (b) (6) Wolinetz, Carrie (NIH/OD) [E]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Hardesty, Rebecca  
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]

**Subject:** ACTIV EC & Working Group Co-Chair Meeting  
**Attachments:** Materials for August 14 ACTIV Executive Committee Teleconference  
**Location:** <https://fnih.zoom.> (b) (6)

**Start:** 8/14/2020 4:00:00 PM  
**End:** 8/14/2020 5:00:00 PM  
**Show Time As:** Busy

**Required Attendees:** Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock,

**Optional  
Attendees:**

Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; Culp, Michelle (NIH/OD) [E]; FNIH Central Account; Gadbois, Ellen (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hardesty, Rebecca (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Lowy, Douglas (NIH/NCI) [E]; Hawk, Harrison; Lucas Smalldon

Shortening calls to 1 hour in length.

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Find your local number: <https://fnih.zoom.us> (b) (6)

**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 6/15/2020 2:29:09 PM  
**To:** Jim Neaton [ (b) (6) ] Jens Lundgren [ (b) (6) ] Eric Hughes [ (b) (6) ] Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Karen Lynn Price [ (b) (6) ] LaVange, Lisa M [ (b) (6) ] Sandeep Menon [ (b) (6) ] Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Rachel Harrigan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80023e7be2dd4554b54d1604fa60df18-rachel.h.ha]; William Erhardt [ (b) (6) ] TTHOMPSON [ (b) (6) ] Gelijns, Annetine [ (b) (6) ] Moskowitz, Alar [ (b) (6) ] Ab Babiker [ (b) (6) ] Cavan, Reilly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=995fe0f1a53c443a832f96f003f0f2c5-cavanr.bios]; Phillips, Andrew [ (b) (6) ] [ (b) (6) ] Birgit Grund [ (b) (6) ] Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f2b26b051964d9da6868e53c9cc6c49-jim.cabr.um]; Joe Koopmeiners [ (b) (6) ] David Vock [ (b) (6) ] Thomas Murray [ (b) (6) ] Max Parmar [ (b) (6) ] Mark Polizzotto [ (b) (6) ] Ginny Kan [ (b) (6) ] Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Baker, Jason [ (b) (6) ] Roger Paredes [ (b) (6) ] [ (b) (6) ] [ (b) (6) ] M [ (b) (6) ] [ (b) (6) ] Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Emilia.bagiell [ (b) (6) ] [ (b) (6) ] Ajay Nirula [nirula\_ajay@lilly.com]; Paul Klekotka [ (b) (6) ]  
**CC:** Demarcus [ (b) (6) ] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) ] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Chen, Helen Q. [ (b) (6) ] Eron, Joseph J Jr [ (b) (6) ] Chew, Kara M.D. [ (b) (6) ] Daar, Eric [ (b) (6) ] Bagiella, Emilia [ (b) (6) ]  
**Subject:** Materials for ACTIV-3 Writing Team 06/15/2020  
**Attachments:** ACTIV\_TX-Clinical\_ACTIV-3 Writing Team Meeting Agenda\_20200615.pdf; INSIGHT014\_ACTIV3\_protocol\_v0.44\_14June2020\_PAK\_Lilly.docx

Dear ACTIV-3 Writing Team,

Please find the agenda for today's meeting and the current version of the protocol.

Thanks,

APAR0000005192-2517046

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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(b) (6) US (Tacoma)

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**From:** Amanda Peppercorn [ (b) (6) ]  
**Sent:** 4/16/2020 12:46:45 PM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) (b) (6) Kristen Neese [ (b) (6) ] Kathleen Quinn [kathleen. (b) (6) ]  
**CC:** Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; John Lepore (b) (6)  
**Subject:** RE: URGENT: Need to know how to reach your comms contacts  
**Flag:** Follow up

Dear Francis, Kristen Neese (cc'd) is the appropriate GSK communications contact.

Many thanks,

*Amanda*

Amanda Peppercorn, M.D.  
GSK Research & Development  
mobile (b) (6)  
email (b) (6)

---

**From:** Collins, Francis (NIH/OD) [E] < (b) (6) >  
**Sent:** Thursday, April 16, 2020 8:28 AM  
**To:** (b) (6) (b) (6) Amanda Peppercorn < (b) (6) >  
**Cc:** Myles, Renate (NIH/OD) [E] < (b) (6) > Meltzer, Abbey (FNIH) [T] < (b) (6) >  
**Subject:** URGENT: Need to know how to reach your comms contacts  
**Importance:** High

EXTERNAL

Hi Tom, William, and Amanda,

Can you provide comms contacts this morning? We are trying to post this press release later today.

Many thanks, Francis

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Thursday, April 16, 2020 8:13 AM  
**To:** (b) (6)  
**Cc:** Myles, Renate (NIH/OD) [E] (b) (6); Parker, Ashley (NIH/OD) [E] < (b) (6) > Burklow, John (NIH/OD) [E] < (b) (6) > Wholley, David (FNIH) [T] < (b) (6) > Meltzer, Abbey (FNIH) [T] (b) (6)  
**Subject:** Need to know how to reach your comms contacts  
**Importance:** High

COLL0000022501-2517047

Dear ACTIV colleagues (once again, that's you in the bcc line):

As I mentioned yesterday, we would like to announce the plans for the ACTIV public-private partnership as expeditiously as possible. Please provide the name of the most appropriate communication contact from your company so that we may share a draft of the embargoed press release for your review. Please send the contact information to Renate Myles at (b) (6) and Abbey Meltzer (b) (6) as soon as possible.

Many thanks, Francis

**GSK monitors email communications sent to and from GSK in order to protect GSK, our employees, customers, suppliers and business partners, from cyber threats and loss of GSK Information. GSK monitoring is conducted with appropriate confidentiality controls and in accordance with local laws and after appropriate consultation.**

**From:** Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]  
**Sent:** 7/21/2020 7:14:01 PM  
**To:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [ (b) (6) Disbrow, Gary (OS/ASPR/BARDA) [ (b) (6) Dolsten, Mikael [ (b) (6) Gibbons, Gary (NIH/NHLBI) [E] [ (b) (6) Marks, Peter (FDA/CBER) [ (b) (6) Pao, William [ (b) (6) Stoffels, Paul [ (b) (6) Woodcock, Janet (FDA/CDER) [ (b) (6) Colvis, Christine (NIH/NCATS) [E] [ (b) (6) Desrosiers, Betsy [ (b) (6) Eric Hughes [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [ (b) (6) Lowy, Douglas (NCI) [ (b) (6) Read, Sarah (NIH/NIAID) [E] [ (b) (6) Young, John [ (b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Plump, Andrew [ (b) (6)  
**CC:** Adam, Stacey (FNIH) [T] [ (b) (6) Alvarez, Rosa [ (b) (6) Anderson, Margaret [ (b) (6) Chen, Helen [ (b) (6) Elsaid, Olivia [ (b) (6) Gonzalez, Nina [ (b) (6) James, Stephanie (FNIH) [T] [ (b) (6) ]; Menetski, Joseph (FNIH) [T] [ (b) (6) Santos, Michael (FNIH) [T] [ (b) (6) Stratton, Benjamin [ (b) (6) Tolman, Brett [ (b) (6) Tountas, Karen (FNIH) [T] [ (b) (6) Wachtel, Jonathan [ (b) (6) ]; Wholley, David (FNIH) [T] [ (b) (6) ]; Anderson, James (NIH/OD) [E] [ (b) (6) Austin, Christopher (NIH/NCATS) [E] [ (b) (6) Burklow, John (NIH/OD) [E] [ (b) (6) Castillejos, Carlos [ (b) (6) Culp, Michelle (NIH/OD) [E] [ (b) (6) FNIH Central Account [ (b) (6) Gadbois, Ellen (NIH/OD) [E] [ (b) (6) Hallett, Adrienne (NIH/OD) [E] [ (b) (6) ]; Lane, Cliff (NIH/NIAID) [E] [ (b) (6) Myles, Renate (NIH/OD) [E] [ (b) (6) Parker, Ashley (NIH/OD) [E] [ (b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Burrus-Shaw, Cyndi (NIH/OD) [E] [ (b) (6) Carver, Trea (NIH) [C] [ (b) (6) ]; Lagos, Enrique (NIH/NCATS) [E] [ (b) (6) ]; Sepulveda, Dorina (FNIH) [T] [ (b) (6) Simon, Dina (NIH/OD) [C] [dina. (b) (6) Gorman, Greta (FNIH) [T] [ (b) (6) Meltzer, Abbey (FNIH) [T] [ (b) (6) Barasch, Kimberly (NIH/NIAID) [C] [ (b) (6) ]; Conrad, Patricia (NIH/NIAID) [E] [ (b) (6) .gov]; Dimishkov, Roxanne (NIH/NHLBI) [C] [ (b) (6) ]; McManus, Ayanna (NIH/OD) [E] [ (b) (6) Perala, Mie [ (b) (6) Protasiewicz, Ann [ (b) (6) Riccobene, Kim [ (b) (6) Thomas, Ashley (FDA/CDER) [ (b) (6) Wood, Gretchen (NIH/OD) [E] [ (b) (6) Togashi, Mieko (NIH/NCI) [E] [ (b) (6) ]; Underwood, Nancy [ (b) (6) Zottoli, Jessica [ (b) (6) Lowy, Douglas (NIH/NCI) [E] [ (b) (6) Hawk, Harrison [ (b) (6) Lucas Smalldon [ (b) (6) Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Hardesty, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]  
**Subject:** ACTIV EC & Working Group Co-Chair Meeting  
**Location:** <https://fnih.zoom.us/j/91811500000> (b) (6)  
**Start:** 8/14/2020 4:00:00 PM  
**End:** 8/14/2020 5:00:00 PM  
**Show Time As:** Busy  
  
**Required Attendees:** Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock,



**Optional  
Attendees:**

Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; Culp, Michelle (NIH/OD) [E]; FNIH Central Account; Gadbois, Ellen (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hardesty, Rebecca (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Lowy, Douglas (NIH/NCI) [E]; Hawk, Harrison; Lucas Smalldon

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**From:** Florence, Clint (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E032D0BC8554E8787E844A7773295FE-FLORENCEWC]  
**Sent:** 9/29/2020 6:03:32 PM  
**To:** Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m; (b) (6) Annaliesa. (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) ; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [ (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [ (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Isis. (b) (6) (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim,



Elizabeth [ (b) (6) ] btolman [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan [ (b) (6) ] Prabhavathi  
Fernandes [ (b) (6) ] Rose Li [ (b) (6) ] Dana Carluccio  
[ (b) (6) ] Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange  
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos];  
Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Simon, Dina (NIH/OD) [C]  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi  
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D  
[ (b) (6) ] Dave Frankowski [ (b) (6) ] Baric, Toni C  
[ (b) (6) ] Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative  
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint  
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188];  
Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James  
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8];  
Mason, Stephen [ (b) (6) ] Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange  
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa];  
[ (b) (6) ] Diamond, Michael [ (b) (6) ] Gonzalez, Nina  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]  
**Subject:** Re: ACTIV Preclinical full working group

All –

(b) (4)

(b) (4)

Thanks –

Clint

---

**From:** (b) (6)

**When:** 10:00 AM - 11:00 AM September 30, 2020

**Subject:** ACTIV Preclinical full working group

**Location:** <https://fnih.zoom.us> (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]  
Sent: 7/23/2020 3:56:22 PM  
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Alison C. Roxby [ (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieri]; Bascles, Lionel [ (b) (6) Baseler, Beth (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2363525c118a468b9e8f5f61707c63f5-bbaseler]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Elizabeth A. [ (b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Draghia-Akli, Ruxandra [ (b) (6) Eaton, Niles [ (b) (6) Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d66f248268d2edec566c26c2a-gadboisel]; Garner, Carlos [ (b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Grace, Beth (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75f1e9e678842258cf6472505f68cd8-bgrace]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Hudson, Fleur [ (b) (6) Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Kan, Virginia [ (b) (6) Karg, Carissa B [ (b) (6) Barrett, Kevin (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0490b8cf48984327b737d027f4fddd81-barrettk2]; Krapp, Katharina [ (b) (6) Krauss, Randy D. [ (b) (6) Kublin, James [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Lee, Marina (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98ee193dbee74e9bb92f2ef0f1753543-leemarina]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Martinez, Mary Lin [ (b) (6) McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group



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[ (b) (6) Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange  
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]

CC: Wachtel, Jonathan [ (b) (6) ]  
Subject: ACTIV CTC Dashboard Quick Reference Guide  
Attachments: CTC Dashboard Quick Reference Guide.pdf

Dear ACTIV Capacity Dashboard/GeoTracker Tool Users,

Attached is a hot-off-the-presses high-level guide to using the ACTIV Clinical Trial GeoTracking Tool.  
Hope you find this helpful, but feel free to reach out if you have any questions.

If you haven't used the dashboard lately, you may notice changes to the look and improvements to a variety of features --  
enjoy! Login links may be found at the bottom of the guide.

Best regards,  
Karen

**Karen H. Tountas, PhD**  
Scientific Program Manager  
**Foundation for the National Institutes of Health**  
(b) (6) | [fnihi.org](https://fnihi.org)  
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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GADB0000002800-2517050



**From:** George, Jill (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F90BFFB4B3A2464382ADC29B127AED4E-GEORGEJIL]  
**Sent:** 9/9/2020 6:29:00 PM  
**To:** Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]  
**Subject:** RE: ACTIV Therapeutics-Clinical Working Group Meeting

Right. Not in PDF.

-----Original Message-----

**From:** Parker, Ashley (NIH/OD) [E] <ashley.parke (b) (6)>  
**Sent:** Wednesday, September 9, 2020 2:00 PM  
**To:** George, Jill (NIH/OD) [E] <(b) (6)> Brodd, Lauren (NIH/OD) [E] <(b) (6)>  
**Subject:** RE: ACTIV Therapeutics-Clinical Working Group Meeting

No -- I thought we had a PDF version that worked fine before but maybe not. Does the hover over not work in PDF? If so, I will let the group know.

Thanks,  
Ashley

-----Original Message-----

**From:** George, Jill (NIH/OD) [E] <(b) (6)>  
**Sent:** Wednesday, September 9, 2020 1:49 PM  
**To:** Parker, Ashley (NIH/OD) [E] <(b) (6)> Brodd, Lauren (NIH/OD) [E] <(b) (6)>  
**Subject:** RE: ACTIV Therapeutics-Clinical Working Group Meeting

Did you figure out how to make hover over work in a PDF?  
The PPTX file is working fine.

-----Original Message-----

**From:** Parker, Ashley (NIH/OD) [E] <(b) (6)>  
**Sent:** Wednesday, September 9, 2020 1:45 PM  
**To:** George, Jill (NIH/OD) [E] <(b) (6)> Brodd, Lauren (NIH/OD) [E] <(b) (6)>  
**Subject:** RE: ACTIV Therapeutics-Clinical Working Group Meeting

Hi Jill and Lauren,

The clinical trial matrix is out for review by the ACTIV Tx working group.

Jill -- Helen shared the attached PDF and I noticed the hover over does not work. I am not concerned about this issue given it's the WG reviewing but wanted to flag in case something needs to be tweaked in the PP file attached for future sharing using PDF.

Thanks,  
Ashley

-----Original Message-----

**From:** Chen, Helen Q. <(b) (6)>  
**Sent:** Wednesday, September 9, 2020 1:27 PM  
**To:** Adam, Stacey (FNIH) [T] <(b) (6)> Bozzette, Sam (NIH/NCATS) [E] <(b) (6)>  
Butterton, Joan <(b) (6)> ; De Claro, R. Angelo (FDA/CDER) <(b) (6)>  
Dradhia-Akli, Ruxandra <(b) (6)> Eisner, Mark <(b) (6)> Gottesdiener, Keith  
<(b) (6)> Eric Hughes <(b) (6)> ; Judy Currier  
<(b) (6)> Kim, Elizabeth <(b) (6)> LaVange, Lisa <(b) (6)>  
Levy, Elliot <(b) (6)> Mellors, John W <(b) (6)> Menon, Sandeep  
<(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Patel, Naimish  
<naimish.patel@sanofi.com> Peppercorn, Amanda <amanda.f. (b) (6)> Poole, Mike  
<(b) (6)> ; Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Read, Sarah  
(NIH/NIAID) [E] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Shen, Yuan Li  
(FDA/CDER) <(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> Wholley, David  
(FNIH) [T] <(b) (6)> ; Buchman, Tim (OS/ASPR/BARDA) (CTR) <Tim.Buchman@hhs.gov>; Collins, Sylvia  
(FDA/CDER) <(b) (6)> Amanda Peppercorn <amanda. (b) (6)> Garner, Carl  
<ga (b) (6)> Higgs, Elizabeth (NIH/NIAID) [E] <(b) (6)> Koroshetz, Walter  
(NIH/NINDS) [E] <(b) (6)> ; Timothy Burgess <(b) (6)> uo: Reineck, Lora  
(NIH/NHLBI) [E] <(b) (6)> Aggarwal, Neil (NIH/NHLBI) [E] <(b) (6)>  
Rosenberg, Yves (NIH/NHLBI) [E] <(b) (6)> Goff, David (NIH/NHLBI) [E]  
(b) (6) Brown, Jeremy (NIH/NINDS) [E] <(b) (6)> Gadbois, Ellen (NIH/OD) [E]





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**Sent:** 6/18/2020 12:07:43 PM  
**To:** Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]  
**Subject:** RE: ACTIV rosters for website

Hi Lauren,

Thank you for doing this – I will follow up with Cheryl to see if we can get more information on the discrepancies you've identified.

Please see additional responses in red below.

---

**From:** Brodd, Lauren (NIH/OD) [E] <(b) (6)>  
**Sent:** Wednesday, June 17, 2020 6:42 PM  
**To:** Parker, Ashley (NIH/OD) [E] <(b) (6)>  
**Subject:** ACTIV rosters for website

Hi Ashley,

I compared the WG rosters (using file "ACTIV Working Group Rosters- MASTER" from Cheryl's email yesterday, below and attached) to the website. Few things:

- **Preclinical Working Group:** Damon Deming is listed on the Master excel file, but not on the website.
- **Therapeutics Clinical Working Group:** David Goff and Yves Rosenberg are both listed on the website, but not in the Master excel file.
  - Note: on the website, David Goff is listed for both the Therapeutics Clinical and the Clinical Trial Capacity WGs (not on both in the excel sheet).
- **Vaccines Working Group:** Gregory Glenn is listed on the Master excel file, but not on the website.
- The only addition for WG members that I have seen through email is Therese Takas. She is both listed in the excel file and on the website.
- I compared the names listed in the ACTIV WG Rosters- MASTER file with the website. Is there anything else I should be looking for/comparing aside from the names of WG members (such as members of the leadership/executive committees, or participating companies)? Yes, please compare the EC members listed and company names with those listed on the website – ACTIVleadership is not listed on the website. And do I need to do anything with the "Master and WG Email list for ACTIV" file? I think it would be useful to update the current master email spreadsheet or create a new one to include 1. EC tab (name, position, company, and email), 2. leadership tab (name, position, company, and email), and 3. company only tab with list of alphabetized company names – this will make it easier to compare moving forward. It may also be a good idea to make sure the names/emails in the master match those listed for the working group rosters (they are prepared by different staff at FNIH and we've had issues with those not matching previously).

Thanks,

Lauren

---

**From:** Melencio, Cheryl (FNIH) [T] <(b) (6)>  
**Sent:** Tuesday, June 16, 2020 8:59 AM  
**To:** Parker, Ashley (NIH/OD) [E] <(b) (6)>  
**Cc:** Brodd, Lauren (NIH/OD) [E]  
**Subject:** RE: Intro to Lauren Brodd



Nice to meet you Lauren. Enclosed are the spreadsheets and I will send them each Friday.

Cheryl

**Cheryl Melencio**

Administrative Manager, Research Partnerships

Foundation for the National Institutes of Health

(b) (6)

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**From:** Parker, Ashley (NIH/OD) [E] <(b) (6)>

**Sent:** Tuesday, June 16, 2020 8:56 AM

**To:** Melencio, Cheryl (FNIH) [T] (b) (6)

**Cc:** Brodd, Lauren (NIH/OD) [E]

**Subject:** Intro to Lauren Brodd

Good morning Cheryl,

I hope you are off to a great start this week! I want to virtually introduce you to Lauren Brodd, cc'd here – Lauren will be working with Renate and myself on the ACTIV communications for the NIH website. I would like to ensure that she also receives the updates for members who are added to the working groups and companies who may continue to join – this will help us with keeping our website up to date.

I informed Lauren of our weekly receipt of the two spreadsheets, one with emails that you've managed and the other with the list of working groups managed by the FNIH COMMs. If you could share any updates to these spreadsheets that would be great (these were last received on June 3<sup>rd</sup>) and we will look forward to our regular updates on Fridays.

Thank you,  
Ashley

**Ashley Parker, Ph.D.**

**Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)**

**Office of the Director | National Institutes of Health**

**Tel:** (b) (6)



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**From:** Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]  
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kayvon.modjarrad.civ@mail.mil; Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som]; Offit, Paul  
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USARMY MEDCOM WRAIR (USA) [ (b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange  
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Thornburg, Natalie  
(CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group  
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];  
'Wachtel, Jonathan' [ (b) (6) Stratton, Benjamin [ (b) (6) Anderson, Margaret  
[ (b) (6) (b) (6) : (b) (6) Bethany Stokes  
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[/o=ExchangeLabs/ou=Exchange Administrative Group  
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[ (b) (6) Isabel Ramsey [ (b) (6) Sridhar, Saranya /US  
[ (b) (6) Brian Rosen [ (b) (6) Cheryl Keech [ (b) (6) Sadoff,  
Jerald [JRDUS] [ (b) (6) Michael, Nelson [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=05b9ca6b24634974b7aeb3fcaead1623-nmichael.hi]; Kayvon Modjarrad  
[ (b) (6)

**Subject:** Notes and materials from the Vaccines Working Group meeting

**Attachments:** 2020-07-01 Vaccines Working Group meeting Summary Notes.docx; 20200701 Vaccines Working Group Meeting.pptx; SARS-CoV-2 Vaccine Development - Role of CHIMs - NEJM - 2020.pdf

Dear Vaccines Working Group and Vaccines Clinical Trials Sub-Group members,

Thank you for your participation in the Vaccines Working Group meeting, and particular thanks to Doug and Larry for leading the conversation and fostering extensive input from the group.

Attached are the meeting notes, materials, and the NEJM Perspective published on behalf of the Working Group on Wednesday.

As always, please reach out with any updates, questions or suggestions.

Best regards,  
Brett and Mike

Michael Santos, PhD  
Associate Vice President, Science | Foundation for the National Institutes of Health

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**From:** Santos, Michael (FNIH) [T]  
**Sent:** Tuesday, June 30, 2020 1:02 PM  
**Subject:** Agenda for the Vaccines Working Group meeting tomorrow

Dear Vaccines Working Group and Vaccines Clinical Trials Sub-Group members,

The agenda topic for tomorrow's meeting of the Vaccines Working Group (Wednesday, 10:30am ET / 7:30am PT / 4:30pm CEST) will be the disparities in the burden of COVID-19 on sub-populations and the implications for representation of sub-populations in efficacy trials.

Given the topic, we are adding the members of the Vaccines Clinical Trials Sub-Group to the invite: you are welcome to join the meeting. We will still have Thursday's meeting of the Vaccines Clinical Trials Sub-Group as planned, on the topic of testing COVID vaccines in pregnant women in bridging studies.

We are looking forward to your participation. Please don't hesitate to reach out with any questions or suggestions.

Best regards,  
Brett and Mike

**Michael Santos, PhD**  
Associate Vice President, Science  
**Foundation for the National Institutes of Health**  
(b) (6) | [fnih.org](https://fnih.org)  
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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**From:** LaVange, Lisa M [ (b) (6) ]  
**Sent:** 1/23/2021 6:32:31 PM  
**To:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan\_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [ (b) (6) ]; Gottesdiener, Keith [ (b) (6) ]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [ (b) (6) ]; Levy, Elliot [ (b) (6) ]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [ (b) (6) ]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [ (b) (6) ]; Peppercorn, Amanda [ (b) (6) ]; Poole, Mike [ (b) (6) ]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collis]; Amanda Peppercorn [ (b) (6) ]; Garner, Carl [ (b) (6) ]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96c8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner



[ (b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [ (b) (6) Petrovick, Martha - 0449 - MITLL [ (b) (6) (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Larry Tsai [ (b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Jansen, Kathrin [ (b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [ (b) (6) Biggs, Mary [ (b) (6) Butcher, Tina [ (b) (6) DeMarcus, Forrest [ (b) (6) Macone, Erin [ (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [ (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Dana Carluccio [ (b) (6) Rose Li Central Account [ (b) (6) Lucas Smalldon [ (b) (6) jennifer.j. [ (b) (6) Mollica, Linda /US [ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Wung, Peter /US [ (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [ (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [ (b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bdfd32930-walkerp1]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact\_f12]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]

**Subject:** RE: Summary of the ACTIV Therapeutics-Clinical Working Group

Very nice announcement and impressive data analysis utilizing patients from three different platform trials. Congrats to the ACTIV-4 team!  
Lisa

**From:** Adam, Stacey (FNIH) [T] < (b) (6) >  
**Sent:** Friday, January 22, 2021 3:50 PM

**To:** Bozzette, Sam (NIH/NCATS) [E] <(b) (6)> Butterson, Joan <(b) (6)> De Claro, R. Angelo (FDA/CDER) <(b) (6)> Draghia-Akli, Ruxandra <(b) (6)> Gottesdiener, Keith <(b) (6)> Eric Hughes <(b) (6)> Judy Currier <(b) (6)> Kim, Elizabeth <(b) (6)> LaVange, Lisa M <lisa.(b) (6)> Levy, Elliot <(b) (6)> Mellors, John W <(b) (6)> Menon, Sandeep <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Patel, Naimish <(b) (6)> Peppercorn, Amanda <(b) (6)> Poole, Mike <(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Shen, Yuan Li (FDA/CDER) <(b) (6)> Stein, Peter (FDA/CDER) <Peter.Stein@fda.hhs.gov>; Wholley, David (FNIH) [T] <(b) (6)> Buchman, Tim (OS/ASPR/BARDA) (CTR) <(b) (6)> Collins, Sylva (FDA/CDER) <(b) (6)> Amanda Peppercorn <(b) (6)> Garner, Carl <(b) (6)> Higgs, Elizabeth (NIH/NIAID) [E] <(b) (6)> Koroshetz, Walter (NIH/NINDS) [E] <(b) (6)> Timothy Burgess <t(b) (6)> Reineck, Lora (NIH/NHLBI) [E] <(b) (6)> Aggarwal, Neil (NIH/NHLBI) [E] <(b) (6)> Rosenberg, Yves (NIH/NHLBI) [E] <(b) (6)> Goff, David (NIH/NHLBI) [E] <(b) (6)> Brown, Jeremy (NIH/NINDS) [E] <(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)> Jacqueline Kirchner <(b) (6)> Beigel, John (NIH) [E] <(b) (6)> Phillips, L Revell CIV DTRA RD (USA) <(b) (6)> Petrovick, Martha - 0449 - MITLL <(b) (6)> (b) (6) : Sizemore, Christine (NIH/FIC) [E] <(b) (6)> Larry Tsai <(b) (6)>

**Cc:** Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Jansen, Kathrin <(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Young, John <(b) (6)> Biggs, Mary <(b) (6)> Butcher, Tina <(b) (6)> DeMarcus, Forrest <(b) (6)> Macone, Erin <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)> Salathin, Carla <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Dana Carluccio <(b) (6)> Rose Li Central Account <(b) (6)> Lucas Smalldon <(b) (6)> Mollica, Linda /US <(b) (6)> Qashu, Felicia (NIH/OD) [E] <felicia.(b) (6)> Patterson, Amy (NIH/NHLBI) [E] <(b) (6)> Rubin, Daniel B. (FDA/CDER) <daniel.rubin@fda.hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <(b) (6)> Chen, Helen <(b) (6)> Wung, Peter /US <(b) (6)> Hoots, W. Keith (NIH/NHLBI) [E] <(b) (6)> Groesch, Mary (NIH/NHLBI) [E] <(b) (6)> Shipp, Allan (NIH/NHLBI) [E] <(b) (6)> Kindzelski, Andrei (NIH/NHLBI) [E] <(b) (6)> Hone, David M (Dave) CIV DTRA J9 (USA) <(b) (6)> Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) <(b) (6)> Walker, Paula (NIH/NINDS) [E] <(b) (6)> Sorosa, Alex <(b) (6)> Lumsden, Joanne (NIH/NCATS) [C] <(b) (6)> Lerner, Andrea (NIH/NIAID) [E] <(b) (6)> Embry, Alan (NIH/NIAID) [E] <(b) (6)>

**Subject:** Summary of the ACTIV Therapeutics-Clinical Working Group

Dear ACTIV TX-Clinical WG Members,

Thank you all for a good meeting yesterday and a good discussion on the upcoming variant work. Your feedback was helpful. Please find attached the summary of the meeting. If you have any additions or amendments, please let me know.

In addition, we wanted to share with you breaking news today. The ACTIV-4a trial has it first results for moderately ill patients.

<https://www.nih.gov/news-events/news-releases/full-dose-blood-thinners-decreased-need-life-support-improved-outcome-hospitalized-covid-19-patients>

We will be inviting in Judith Hochman, the PI of ACTIV-4a, to present on these results at a future TX-Clinical WG.

I hope you all have a great weekend!



Kind regards,  
Stacey

**Stacey J. Adam, PhD**

Director, Cancer

Research Partnerships

**Foundation for the National Institutes of Health**

Direct: (b) (6) | Mobile: (b) (6)

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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852





**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 5/6/2020 2:35:42 AM  
**To:** Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan\_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [ (b) (6) Keith Gottesdiener [ (b) (6) Eric Hughes [ (b) (6) LaVange, Lisa M [ (b) (6) Elliott Levy [ (b) (6) Sandeep Menon [ (b) (6) Amanda Peppercorn [amanda.f. (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [ (b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [ (b) (6) Wung, Peter /US [ (b) (6) Karen Lynn Price [ (b) (6) Pamela Tenaerts, M.D. [ (b) (6) Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]  
**CC:** Mary Biggs [ (b) (6) Demarcus [ (b) (6) Macone, Erin [ (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) Elizabeth Kim [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]  
**Subject:** Follow-up from ACTIV TX-Clinical Master Protocol Ad Hoc Meeting  
**Attachments:** ACTIV\_Therapeutics-Clinical\_MP Sub-Group Meeting\_Key Takeaways\_05052020.pdf

Dear TX-Clinical Master Protocols Subgroup,

Please find attached the quick capture summary and action items from our meeting today. If you have any additions or amendments, don't hesitate to let us know.